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IN THE

Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

vs.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants.

On Appeal from the Court of Appeal of the State of California

First Appellate District

JURISDICTIONAL STATEMENT

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JURISDICTIONAL STATEMENT

This is a jurisdictional statement submitted in support of the appeal of Dahlberg Electronics, Inc. and Detection Sciences, Inc. (hereinafter collectively referred to as "Appellant").[1]

The format of this statement will conform to the order, lettering and numbering of Rule 15, to the extent applicable.

[1]Appellant Dahlberg Electronics, Inc. is a subsidiary of appellant Detection Sciences, Inc. For literary convenience, they are hereinafter referred to simply as "Appellant."

(a) Opinion below

The opinion of the Court of Appeal of the State of California is reported in 78 Cal.App.3d 951, 144 Cal.Rptr. 585. A copy of the opinion is also appended hereto as Exhibit A.

(b) Jurisdiction

(i) The Nature of the Proceedings and the Statutes pursuant to which they were brought.

This is an action for injunction brought pursuant to California Health and Safety Code Section 26463(m). The Superior Court of the State of California in and for the County of Santa Cruz issued an injunction which prohibits appellant from advertising that the hearing aids which it manufactures have any effect on hearing loss or deafness.

(ii) Judgment of the State Court.

The judgment of the Superior Court by which the injunction was issued was dated March 17, 1976 and entered March 22, 1976 in Judgment Book, Volume 148, page 220. Appellant filed a Notice of Appeal to the Court of Appeal of the State of California on May 19, 1976. The Court of Appeal's opinion was filed on March 21, 1978. The Court of Appeal denied a petition for rehearing on April 14, 1978. Appellant filed a petition for hearing in the Supreme Court of the State of California on May 1, 1978. The petition was denied on June 15, 1978 and the judgment of the Court of Appeal became final on that date. *American Ry. Exp. Co. v. Levee* (1923) 263 U.S. 19, 68 L.Ed. 140, 44 S.Ct. 11.

Notice of Appeal to this Court was filed in the Court of Appeal on September 1, 1978.

(iii) The Statutory Provisions Conferring Jurisdiction On This Court.

Jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257(2).

(iv) Cases which Sustain the Jurisdiction.

The decision of the Court of Appeal sustained the validity of the California statute as against appellant's claim that it violates the Constitution and laws of the United States. This decision has become final and therefore an appeal to this Court lies as a matter of right. *Huffman v. Pursue, Ltd.*, 420 U.S. 592, 43 L.Ed.2d 482, 95 S.Ct. 1200, rehearing denied 421 U.S. 971, 44 L.Ed.2d 463, 95 S.Ct. 1969.

Should this Court determine that an appeal does not lie, then appellant requests that this appeal and jurisdictional statement be treated as a petition for writ of certiorari.

(v) Statutes Involved.

This appeal involves California Health and Safety Code Section 26463(m) which states that:

> "It is unlawful for any person to advertise any drug or device represented to have any effect on any of the following conditions:
>
> . . .
>
> (m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." (Calif. Stat. 1970, c. 1573, p. 3252 § 5, Amended, Calif. Stats. 1971, c. 646, p. 1272, § 16).

Also involved is California Health and Safety Code Section 26465 which states:

> "Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the condi-

tions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health." (Calif. Stats. 1970, c. 1573, p. 3253, § 5.)

(c) Questions Presented

(1) Whether California Health and Safety Code Section 26463(m) has been pre-empted by the Food, Drug and Cosmetics Act (21 U.S.C. § 301 et seq.) as amended by the Medical Device Amendments of 1976 (21 U.S.C. § 360k).

(2) Whether a state statute and an injunction issued pursuant thereto prohibiting a hearing aid manufacturer from making any representations regarding the effect of its product on hearing loss or deafness are repugnant to the First Amendment to the United States Constitution.

(d) Statement of the Case

Appellees are individuals who claim to suffer from hearing loss.

This matter came before the Superior Court on appellees' motion for injunction by summary judgment. The motion was supported by copies of certain advertisements published by appellant. The basis of appellees' motion was that the advertisements violated Section 26463(m) of the California Health and Safety Code.

The Superior Court made its decision solely on the basis of the advertisements submitted and its interpretation of the statute. The Superior Court made no finding that the advertisements submitted were false or misleading.

The injunction which the court issued was not directed to the particular advertisements before it, but to any and

all advertising regarding the effectiveness of a hearing aid. It states:

> It Is Ordered, Adjudged And Decreed . . . that Defendants be and they hereby are permanently enjoined and restrained from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and deafness. (Tr. 308.)

The court also stated in its "Findings of Fact and Conclusions of Law":

> The use of the term hearing aid in and of itself is not a violation of Section 26463(m), and nothing contained therein precludes defendants or their dealers from advertising their place of business, that Dahlberg hearing aids are sold there, the prices of the hearing aids or any other information of that nature. (Tr. 305-6.)[2]

In order to understand the full significance of the injunction, the statutory definition of "advertisement" must be kept in mind.

> "Advertisement" means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase or use of any food, drug, device or cosmetic. (California Health and Safety Code Section 26002.)

The Court of Appeal affirmed the judgment. It rejected appellant's contention that the statute should be narrowly construed so as to prohibit only false and misleading claims. It held that the statute prohibits not only false and misleading representations that a hearing aid will cure

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[2]In view of the use of the summary judgment procedure, the making of findings of fact and conclusions of law was erroneous under California law. (Calif. Code of Civil Procedure Section 437c.)

hearing loss, but also truthful representations that a hearing aid may have a compensatory effect on hearing loss. The opinion states:

> "The statute is clear and unambiguous and does not exempt any so-called "compensatory effect." There is an exception included in the [California] Sherman Food, Drug and Cosmetics Law, which authorizes advertising of drugs and devices having a curative or therapeutic effect under certain conditions (§ 26465),[ ] however, this section makes no mention of compensatory effect and there is no claim by defendants that they had received any such authorization from the department exempting their product." (Opinion, pp. 3-4.)

The Court of Appeal's construction of the statute is binding on this Court. *U.S. v. Thirty-Seven (37) Photographs*, 402 U.S. 363, 28 L.Ed.2d 822, 91 S.Ct. 1400, rehearing denied 403 U.S. 924, 29 L.Ed.2d 702, 91 S.Ct. 2221.

The Court of Appeal also rejected appellant's contention that Section 26463(m) was pre-empted by federal law and regulation. In so doing, it held that the subject statute was a "prohibition" and not a "requirement" and that hearing aids were not "restricted devices" within the meaning of 21 U.S.C. § 352(r). These distinctions and terminology are discussed in detail below.

Finally, the Court of Appeal also held that the subject statute, as construed and applied by it, did not deny freedom of speech as guaranteed by the First Amendment. It based this holding upon its own independent finding of fact that ". . . the copies of the advertisements that are included in the record . . . were misleading in that they convey the impression that the hearing aid would have a curative or therapeutic effect." (Opinion, p. 5). It is essential to note, however, that the injunction was not limited to the particular advertisements in the record but covers

all advertising. Therefore, the court's conclusion, even if true, does not support its holding.

Appellant made its contentions that the statute was pre-empted and that it was unconstitutional for the first time in the Court of Appeal. They were not made in the Superior Court because the federal law had not yet been enacted and because this Courts' decision in *Virginia State Board of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc.* (1976) 425 U.S. 748, 48 L.Ed.2d 346, 96 S.Ct. 1817, had not yet been announced.

(e) The Questions Are Substantial

I. The statute has been pre-empted.

Section 26463(m) was clearly pre-empted by federal statute and regulations enacted and promulgated during the pendency of this appeal. The federal statute and regulations were called to the attention of the Court of Appeal in appellant's closing brief. The court agreed that the pre-emption issue was timely raised, (see *Meier v. Ross General Hospital* (1968) 69 Cal.2d 420, 423 (footnote 1); 71 Cal.Rptr. 903; *Cal-Dak Co. v. Sav-On-Drugs* (1953) 40 Cal. 2d 492, 496-497, 254 P.2d 497) but held that pre-emption had not occurred.

The error in this conclusion is readily apparent from an examination of the federal statute and regulations.

1. On May 28, 1976 the Medical Device Amendments of 1976 (P.L. 94-295) became law. The new law amended the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq., hereinafter "Act"). New section 521 of the Act (21 U.S.C. 360k) states that:

> **"Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may estab-**

lish or continue in effect with respect to a device intended for human use any requirement—

(1) which is *different from, or in addition to,* any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Exempt Requirements

(b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not not cause the device to be in violation of any applicable requirements under this Act." (Emphasis added.)

2. New section 520(e) of the Act (21 U.S.C. 360j(e)(1)) states that the Secretary of Health, Education and Welfare may adopt regulations which restrict the sale, distribution or use of medical devices. Upon the adoption of such regulations, these devices are then known as "restricted devices."

3. On February 10, 1977 the Food and Drug Administration of the United States Department of Health, Education and Welfare (FDA) adopted new Rules and Regulations pertaining to hearing aid devices. (42 Fed. Reg. No. 31.) The regulations took effect on August 15, 1977. These regulations classify hearing aids as "restricted devices."[3]

4. Because hearing aids are "restricted devices" they are covered by the provisions of 21 U.S.C. § 352 pertaining to "misbranded drugs and devices." This section of the Act states in pertinent part that,

"A drug or device shall be deemed to be misbranded—...

(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer or distributer thereof includes in *all advertisements . . . a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contra-indications . . . .*" (Emphasis added.)

The Court of Appeal based its conclusion that pre-emption had not occurred upon two grounds: (a) that section 26463(m) embodies a "prohibition" rather than a "requirement" as referred to in 21 U.S.C. § 360k; and (b) that hearing aids are not "restricted devices." (See Opinion, p. 8.) Neither of these grounds has any validity.

A. The statute imposes a requirement "different from" and "in addition to" that of the federal act and is not a mere prohibition.

The first ground is a purely superficial distinction, based strictly upon semantics, and drawn without any regard to the intent of the Act. The language of 21 U.S.C. § 352(r)

[3]The Food and Drug Administration specifically stated when publishing the regulations that "Upon the effective date of the regulation, hearing aids will become 'restricted devices' under section 520(e) of the Federal Food, Drug and Cosmetic Act." (See 42 Fed.Reg. No. 31, at page 9291.)

reveals a clear intent to control the content of "all advertisements" of a "restricted device." Such advertisements *must contain* "a brief description of the intended uses of the device."

The intent of Congress is clearly contravened by any state law purporting to prohibit the manufacturer of a "restricted device" from describing its intended use. Yet this is precisely what section 26463(m), as construed by both the Superior Court and the Court of Appeal herein, does. It prohibits the hearing aid manufacturer from representing that the aid has "any effect," even a compensatory effect, on hearing loss. To say that this is only a "prohibition" as opposed to a "requirement" is to elevate form over substance. It requires one to indulge in the unrealistic assumption that hearing aids will simply not be advertised. Such assumption is not only naive, it is also contrary to the clear policy of Congress that such advertising is desirable. (See discussion, section D infra.) The statute is therefore "different from" and "in addition to" the Act.

The distinction which the Court of Appeal sets up is contrary to this Court's guidelines for determining whether pre-emption has occurred. As stated by this Court in *Jones v. Rath Packaging Co.* (1977) 430 U.S. 519, 51 L.Ed.2d 604, 97 S.Ct. 1305,

> Where, as here, the field which Congress is said to have pre-empted has been traditionally occupied by the States, see, eg., U.S. Const Art I, § 10; Patapsco Guano Co. v. North Carolina, 171 US 345, 358, 43 L Ed 191, 18 S Ct 862 (1898), "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Rice v Santa Fe Elevator Corp. 331 US 218, 230, 91 L Ed 1447, 67 S Ct 1146 (1947). This assumption provides assurance that "the federal-state balance," United States v Bass, 404 US 336, 349, 30 L Ed 2d 488, 92 S Ct 515 (1971),

> will not be disturbed unintentionally by Congress or unnecessarily by the courts. But when Congress has "unmistakably . . . ordained," Florida Lime & Avocado Growers, Inc. v Paul, 373 US 132, 142, 10 L Ed 2d 248, 83 S Ct 1210 (1963), that its enactments alone are to regulate a part of commerce, state laws regulating that aspect of commerce must fall. This result is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. City of Burbank v Lockheed Air Terminal, Inc. 411 US 624, 633, 36 L Ed 2d 547, 93 S Ct 1854 (1973); Rice v Santa Fe Elevator Corp., supra, at 230, 91 L Ed 1447, 67 S Ct 1146.

In *Jones* certain packages of bacon were ordered removed from sale pursuant to a California weight labelling statute and regulations which required that the average weight of packages in a lot of any commodity shall not be less at the time of sale than the net weight stated on the packages. The company which had packaged the bacon instituted actions against certain state officials seeking an injunction against enforcement of the state laws and a declaration that such laws were pre-empted by federal laws regulating net weight labelling. The California laws made no allowances for reasonable variations from stated weight resulting from loss of moisture during the course of good distribution practices, but the federal law provided that "reasonable variations" between actual weight and the weight stated on the label could be permitted by regulations prescribed by the Secretary of Agriculture and the Secretary's regulations did permit "reasonable variations" resulting from loss of moisture during the course of good distribution practices.

The question presented was basically the same as the one herein; i.e., whether the State of California had attempted to impose "requirements in addition to, or different than," those made under a federal law.[4] The subject statute, section

[4] Federal Meat Inspection Act, as amended by the Wholesale Meat Act, 21 U.S.C. §§ 601 et seq.

12211 of the California Business and Professions Code, was couched in *prohibitory* language, much the same as the state statute herein.[5] Nevertheless, this Court held that it was pre-empted by a "labelling requirement" contained in the federal statute. In so holding, this Court looked to the manifest purpose and objective of the federal law, i.e., to make

[5]"Each sealer shall, from time to time, weigh or measure packages, containers or amounts of commodities sold, or in the process of delivery, in order to determine whether the same contain the quantity or amount represented and whether they are being sold in accordance with law.

"The director [of agriculture] is hereby authorized and directed to adopt and promulgate necessary rules and regulations governing the procedures to be followed by sealers in connection with the weighing or measuring of amounts of commodities in individual packages or containers or lots of such packages or containers, including the procedures for sampling any such lot, and in determining whether any package or container or a lot of such packages or containers complies with the provisions of this section. . . .

"Any such rule or regulation, or amendment thereof, shall be adopted and promulgated by the director in conformity with the provisions of Chapter 4.5 (commencing with Section 11371), of Part 1 of Division 3 of Title 2 of the Government Code; provided, that *the average weight or measure of the packages or containers in a lot of any such commodity sampled shall not be less, at the time of sale or offer for sale, than the net weight or measure stated upon the package,* and provided further, that said rules or regulations applicable to food, as defined in Section 26450 of the Health and Safety Code, insofar as possible, shall not require higher standards and shall not be more restrictive than regulations, if any, promulgated by the Department of Health, Education, and Welfare, Food and Drug Administration, under the provisions of the Federal Food, Drug and Cosmetic Act.

"Any lot or package of any such commodity which conforms to the provisions of this section shall be deemed to be in conformity with the provisions of this division relating to stated net weights or measures.

"Whenever a lot or package of any commodity is found to contain, through the procedures authorized herein, a less amount than that represented, the sealer shall in writing order same off sale and require that an accurate statement of quantity be placed on each such package or container before same may be released for sale by the sealer in writing. The sealer may seize as evidence any package or container which is found to contain a less amount than that represented." (Emphasis added.)

allowances for loss of weight resulting from moisture loss during the course of good distribution practice. It rejected the argument of the county director of weights and measures which was based upon a narrow construction of the term "labelling requirement."

> Petitioner Jones seeks to avoid this result by arguing that the FMIA's provisions governing the accuracy of the required net quantity statements are not "labeling requirements" within the meaning of § 408. He contends that "labeling" refers only to the format and placement of information, not to its content. Requirements relating to accuracy, according to Jones, deal with the problem of misbranding, and § 408 grants the States concurrent jurisdiction over that subject.
>
> We agree with the Court of Appeals that this argument is "strained." 530 F2d, at 1314 n 25. Nothing in the Act suggests the restrictive meaning petitioner ascribes to the phrase "labeling requirements." To the contrary, § 7(b) requires that the product bear specified information, see supra, at 528-529, 51 L Ed 2d 616, and § 1(p) of the FMIA, 21 USC § 601(p) [§ 2, 21 USCS § 601(p)], makes clear that any material bearing that information is part of the product's labeling. It twists the language beyond the breaking point to say that a law mandating that labeling contain certain information is not a "labeling requirement."
>
> We therefore conclude that with respect to Rath's packaged bacon, § 12211 and Art 5 are pre-empted by federal law.

(430 U.S. at p. 532.)

B. Hearing aids have been classified as "restricted devices."

The second ground relied upon which the Court of Appeal predicated its conclusion that pre-emption had not occurred, i.e. that hearing aids are not "restricted devices", need not detain this Court for more than a moment. The FDA, in adopting its regulations expressly

classified hearing aids as "restricted devices". (See 42 Fed. Reg. No. 31, p. 9291.) The FDA is authorized to make this classification. (21 U.S.C. 360j (e)(1).)

C. The statute has not been exempted.

The Court of Appeal's opinion that section 26463(m) has not been pre-empted no doubt came as a surprise to the California Department of Health which filed an application dated July 19, 1976, entitled "Application for Exemption of California Medical Device Requirements from Pre-emption by Federal Medical Device Amendments of 1976 (Section 521(a))" with the Commissioner of Food and Drugs. The application of the Department of Health (which covers many statutes) is still pending before the FDA.

The FDA by notices of February 15, 1977, 42 Fed.Reg. No. 31, page 9186, and July 28, 1978, 43 Fed.Reg. No. 146, page 33182, has tentatively proposed to grant the application, but has invited special comment regarding the subject statute.[6]

D. The statute is in direct conflict with the Act.

The statute prohibits the very advertising which the federal Act and regulations require.

As shown above, the Act specifically requires that all hearing aid advertising *shall* include a brief statement as to intended uses of the device, i.e., what effect it will have.

In addition, the regulations (21 C.F.R. §§ 801.420 and 801.421) impose several other duties upon hearing aid

[6]The FDA's authority to grant or deny an exemption is not questioned. Indeed, Congress may authorize federal administrative agencies to directly pre-empt state laws by the promulgation of administrative regulations. (See, *e.g., Burbank v. Lockheed Air Terminal, Inc.* (1973) 411 U.S. 624, 36 L.Ed.2d 547, 93 S.Ct. 1854.)

manufacturers and distributors. Among these duties, the manufacturer or distributor must develop a User Instructional Brochure and provide a copy thereof to each prospective purchaser of a hearing aid. This brochure *must* contain certain information and warnings, including specific instructions for use of the hearing aid, a statement that a hearing aid will not restore normal hearing, advice that a person suffering from a hearing loss should consult a licensed physician, preferably an ear specialist, before purchasing a hearing aid, and that federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation or signed a waiver thereof. The brochure *must* contain "a statement that in most cases infrequent use of a hearing aid does not permit a user to obtain full benefit from it." (21 C.F.R. § 801.420 (ix).)

These required statements are clearly advertising within the meaning of California Health and Safety Code Section 26002, i.e., they are representations which are likely to induce the purchase of a hearing aid. As such they fall within the scope of the statute and the injunction, and there is a clear conflict between federal and state laws. Therefore, the state law is superseded. U.S. Const., Art. VI.

E. The statute frustrates the full accomplishment of the objectives of Congress.

Even if there were no direct conflicts, the state statute would still be pre-empted for another reason. As *Jones, supra,* reaffirms, a state statute is overridden by a federal statute whenever it would frustrate the full accomplishment of the objectives of Congress. This is precisely the situation in the instant case where the objective of Congress is to stimulate the flow of information regarding the value of hearing aids.

Jones discussed the question of conflicting federal and state legislation in these terms:

> Congressional enactments that do not exclude all state legislation in the same field nevertheless override state laws with which they conflict. U.S. Const, Art VI. The criterion for determining whether state and federal laws are so inconsistent that the state law must give way is firmly established in our decisions. Our task is "*to determine whether, under the circumstances of this particular case, [the State's] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.*" Hines v Davidowitz, 312 US 52, 67, 85 L Ed 581, 61 S Ct 399 (1941). Accord, De Canas v Bica, 424 US 351, 363, 47 L Ed 2d 43, 96 S Ct 933 (1976); Perez v Campbell, 402 US 637, 649, 29 L Ed 2d 233, 91 S Ct 1704 (1971); Florida Lime & Avocado Growers, Inc. v Paul, supra, at 141, 10 L Ed 2d 248, 83 S Ct 1210; id., at 165, 10 L Ed 2d 248, 83 S Ct 1210 (White, J., dissenting). This inquiry requires us to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written. See De Canas v Bica, supra, at 363-365, 47 L Ed 2d 43, 96 S Ct 933; Swift & Co. v Wickham, 230 F Supp 398, 408 (SDNY 1964), appeal dismissed, 382 US 111, 15 L Ed 2d 194, 86 S Ct 258 (1965), affd on further consideration, 364 F2d 241 (CA2 1966), cert denied, 385 US 1036, 17 L Ed 683, 87 S Ct 776 (1967).
>
> (430 U.S. at pp. 525-526, emphasis added.)

See also *Ray v. Atlantic Richfield Company* (1978) ..... U.S. ....., ... L.Ed.2d ....., 98 S.Ct. 988.

The lower courts herein have adopted the position that the law must shield the prospective purchaser from performance claims for hearing aids and have interpreted the statute accordingly. But it is the policy of the federal law and regulations to require the manufacturer to make performance claims, i.e. to tell the customer what the hearing aid will do and at the same time to warn him what it will not do.

In a prefatory statement to the new regulations, the FDA states:

> The Commissioner sees no value in characterizing hearing aid dispensers solely as "sales persons," or in minimizing the importance of "selling" as it relates to motivating persons to try amplification. Often a person with a hearing impairment lacks the motivation to try a hearing aid or believes a social stigma is attached to wearing a hearing aid (Ref. 4). Although there are a number of documented cases of excessive and abusive sales practices, this is not to say that some selling practices and techniques such as a trial-rental or purchase-option plan, which strengthen motivation to try a hearing aid, are inherently bad. When the number of hearing-impaired persons who currently wear hearing aids is contrasted with the number of people in the United States with a hearing impairment who could be helped by a hearing aid, it is clear that many people are reluctant to acknowledge their hearing impairment or to seek assistance. *Ethical selling practices that provide the potential hearing aid user with incentives to try a hearing aid are therefore to be encouraged.* (42 Fed. Reg. No. 31, p. 9387, emphasis added.)

Appellant submits that the state statute, as interpreted and applied herein, clearly " 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the Congress.' " (*Jones v. Rath Packing Co., supra,* p. 526.) It prevents the manufacturer from communicating the intended use and benefit of a hearing aid to the potential user. The objective of the federal law to

reach out to the hard of hearing because of their reluctance to seek help is frustrated by this statute.

II. The statute and injunction infringe upon Appellant's right to freedom of speech under the First Amendment of the United States Constitution.

1. Commercial speech is protected by the First Amendment to the United States Constitution.

This Court has recently established the principle that "commercial speech" is protected by the First Amendment to the United States Constitution. *Virginia State Board of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc.* (1976) 425 U.S. 748, 48 L.Ed.2d 346, 96 S.Ct. 1817 (hereinafter referred to as "the Virginia case").[7] In the *Virginia* case, a consumer organization brought suit against the Virginia State Board of Pharmacy challenging the validity under the First and Fourteenth Amendments of a Virginia statute declaring it to be unprofessional conduct for a licensed pharmacist to advertise the prices of prescription drugs. This Court struck down the statute in an opinion which states, in part:

> Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what

[7]Subsequent to the *Virginia* case, numerous additional cases have sustained free speech claims for advertising. *E.g., Bates v. Arizona State Bar*, 433 U.S. 350, 53 L.Ed.2d 810, 97 S.Ct. 269-1; *Linmark Associates, Inc. v. Township of Willingboro*, U.S. , 52 L.Ed.2d 55, 97 S.Ct. 1614; *Jacoby v. State Bar of California*, 19 Cal. 3d 359, 377, 138 Cal.Rptr. 77; *Board of Medical Examiners v. Terminal-Hudson Electronics*, 73 Cal.App.3d 376, 140 Cal.Rptr. 757; *Health Systems Agency of Northern Virginia v. Virginia State Board of Medicine* (E.D. VA. 1976) 424 F.Supp. 267.

> product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable. (96 S.Ct. p. 1827).

2. The statute and the injunction are overly broad.

A. All representations for the purpose of inducing a purchase are deemed advertising.

The definition of advertising in California Health and Safety Code Section 26002 is extremely broad.

> "Advertisement" means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase or use of any food, drug, device or cosmetic.

This broad-sweeping definition clearly prohibits any and all forms of expression, written or oral, intended to induce a sale to the public of a drug or device of the type mentioned. *People v. Hohensee* (1967) 251 Cal.App.2d 193, 59 Cal.Rptr. 234. Therefore, the effect of Section 26463, as construed and applied in this case, is to prohibit the manufacturer of a hearing aid from informing the consumer what his product does. The seller or distributor is similarly restricted. He can say "I sell hearing aids for one hundred dollars. My store is located at 1 Main Street". But when the customer comes in and asks, "How will it help me?", he has to say, "I'm sorry, but I can't tell you." This restriction is invalid under the *Virginia* case.

B. There is no provision for obtaining permission to advertise a drug or device.

Section 26463 is not mitigated by the provisions of Section 26465 which contemplate the granting of permission to advertise in certain cases, for such permission depends upon the uncontrolled discretion of the Department of Public Health ("department"). Thus, Section 26465 states:

> Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health.

The statute affords no protection at all for the truthful seller of a worthwhile drug or device. The department must first "determine" that it is safe and effective. But there is no requirement that the department hold a hearing to make such determination and no provision for any interested party to obtain such a hearing before any other agency or tribunal. There is not even a duty imposed upon the department to *consider* a particular drug or device.[8]

There is no procedure to review the department's exercise of discretion or even to compel the exercise of *any* discretion. Thus, there is no procedural safeguard against

[8]If the department does determine that a particular type of self-medication is safe and effective, then it is supposed to authorize advertisement thereof "by regulation". The department is authorized in Section 102 to issue regulations pursuant to procedures set forth in the Government Code. Under these provisions, interested parties may petition for the adoption of regulations, but the governmental agency may deny the petition without a hearing. (See Calif. Government Code Secs. 11426 and 11427.)

suppression of truthful information, and this renders the statute unconstitutional.

In addition, Section 26465 would not even be applicable to hearing aids because they are not "curative or therapeutic" devices.

C. The statute prohibits truthful representations as well as false or misleading ones.

Falsity is not an element of the offense proscribed by Section 26463. *Neslen v. Board of Health* (1945) 70 Cal. App.2d 202, 160 P.2d 862.[9]

Accordingly the statute on its face is overbroad and a claim of unconstitutionality on that ground should be entertained. Appellant should be permitted to challenge the constitutionality of the statute without a showing that its particular advertisements were truthful and thus protected.

> Such claims of facial overbreadth have been entertained in cases involving statutes which, by their terms, seek to regulate "only spoken words." Gooding v Wilson, 405 US 518, 520, 31 L Ed 2d 408, 92 S Ct 1103 (1972). See Cohen v California, 403 US 15, 29 L Ed 2d 284, 91 S Ct 1780 (1971); Street v New York, 394 US 576, 22 L Ed 2d 572, 89 S Ct 1354 (1969); Brandenburg v Ohio, 395 US 444, 23 L Ed 2d 430, 89 S Ct 1827 (1969); Chaplinsky v New Hampshire, 315 US 568, 86 L Ed 1031, 62 S Ct 766 (1942). In such cases, it has been the judgment of this Court that the possible harm to society in permitting some unprotected speech to go unpunished is outweighed by the possibility that protected speech of others may be muted and perceived grievances left to fester because of the possible inhibitory effects of overly broad statutes. . . .

[9]False and misleading advertising is covered by another section of the Health and Safety Code, i.e., Section 26460, which states: "It is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular."

Facial overbreadth claims have also been entertained where statutes, by their terms, purport to regulate the time, place, and manner of expressive or communicative conduct, see Grayned v City of Rockford, supra, at 114-121, 33 L Ed 2d 222; Cameron v Johnson, 390 US, at 617-619, 20 L Ed 2d 182; Zwickler v Koota, 389 US 241, 249-250, 19 L Ed 2d 444, 88 S Ct 391 (1967); Thornhill v Alabama, 310 US 88, 84 L Ed 1093, 60 S Ct 736 (1940), and where such conduct has required official approval under laws that delegated standardless discretionary power to local functionaries, resulting in virtually unreviewable prior restraints on First Amendment rights. See Shuttlesworth v Birmingham, 394 US 147, 22 L Ed 2d 162, 89 S Ct 935 (1969); Cox v Louisiana, 379 US 536; 553-558, 13 L Ed 2d 471, 85 S Ct 453 (1965); Kunz v New York, 340 US 290, 95 L Ed 280, 71 S Ct 312 (1951); Lovell v Griffin, 303 US 444, 82 L Ed 949, 58 S Ct 666 (1938).

(*Broadrick v. Oklahoma* (1973) 413 U.S. 601, 37 L.Ed.2d 830, 93 S.Ct. 2908.)

This Court's pronouncements on the doctrine of overbreadth in the newly protected area of commercial speech have heretofore been somewhat guarded. Thus, in *Bates v. State Bar of Arizona,* 433 U.S. 350, 53 L.Ed.2d 810, 97 S.Ct. 2691, the Court stated,

> . . . the justification for the application of overbreadth analysis applies weakly, if at all, in the ordinary commercial context. As was acknowledged in Virginia Pharmacy Board v Virginia Consumer Council, 425 US, at 771 n 24, 48 L Ed 2d 346, 96 S Ct 1817, there are "common-sense differences" between commercial speech and other varieties. See also id., at 775-781, 48 L Ed 2d 346, 96 S Ct 1817 (concurring opinion). Since advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation. (433 U.S. 380-381)

Appellant submits, however, that there are compelling reasons in the instant case for applying the overbreadth doctrine. First, it involves public health and Congress and the FDA have indicated a definite desire to have information regarding the performance of hearing aids disseminated to potential users. The state statute clearly conflicts with the federal Act and frustrates its objective. Secondly, the desired speech is not only "susceptible to being crushed by overbroad regulation", it has *in fact been crushed.* The statute, as construed and applied by the California courts, restrains appellant from *all* performance claim advertising. And of course if appellant is restrained then all other manufacturers will be similarly restrained. Such restraint is intolerable. The state may not use its police power to prohibit *all* performance claim advertising of medical drugs or devices. Less restrictive alternatives, e.g. California Health and Safety Code Section 26460 prohibiting false and misleading advertising, are available to the state. Other reasonable means are also spelled out in the federal regulations, e.g., the requirement of a medical evaluation before a sale may be made.

In an area affecting First Amendment rights precision of regulation is the touchstone, and statutes must be narrowly drawn so that the precise evil is exposed.

Keyishian v. Board of Regents (1967) 385 U.S. 589, 17 L.Ed.2d 629, 87 S.Ct. 675;

Interstate Circuit, Inc. v. Dallas (1968) 390 U.S. 676, 20 L.Ed.2d 225, 88 S.Ct. 1298;

Shuttlesworth v. Birmingham (1968) 394 U.S. 147, 22 L.Ed.2d 162, 89 S.Ct. 935;

Elfbrandt v. Russell (1966) 384 U.S. 11, 16 L.Ed.2d 321, 86 S.Ct. 1238;

Griswold v. Connecticut (1965) 381 U.S. 479, 14 L.Ed. 2d 510, 85 S.Ct. 1678.

Where First Amendment rights are involved, the courts must examine and test statutes more closely than otherwise.

Ashton v. Kentucky (1966) 384 U.S. 195, 16 L.Ed.2d 469, 86 S.Ct. 1407.

Appellant submits that Section 26463 cannot withstand the close scrutiny required by First Amendment standards. It is overbroad on its face and must be struck down.

D. The injunction goes beyond the particular advertising which was exhibited to the court and presents a further problem of overbreadth.

Because the injunction merely paraphrases the statute, it goes beyond the particular advertising which gave rise to the action and is also patently overbroad. Indeed the injunction presents the problem of overbreadth in a more compelling way than the statute standing alone. The overbreadth doctrine permits litigants ". . . to challenge a statute not because their own rights of free expression are violated, but because of a judicial prediction or assumption that the statute's very existence may cause others not before the court to refrain from constitutionally protected speech or expression." *Broadrick v. Oklahoma* (1973) 413 U.S. 601, 612, 37 L.Ed.2d 830, 93 S.Ct. 2908. But here appellant's own right of free expression *is* directly violated by the injunction. Therefore, appellant submits that the overbreadth doctrine becomes all the more applicable herein. As stated in *Carroll v. Commissioners of Princess Anne* (1968) 393 U.S. 175, 183-184, 21 L.Ed.2d 325, 89 S.Ct. 347,

> An order issued in the area of First Amendment rights must be couched in the narrowest terms that will accomplish the pin-pointed objective permitted by constitutional mandate and the essential needs of the public order. In this sensitive field, the State may not employ "means that broadly stifle fundamental personal liberties when the end can be more narrowly achieved." Shelton v. Tucker, 364 U.S. 479, 488, 5 L. Ed.2d 231, 237, 81 S.Ct. 247 (1969). In other words, the order must be tailored as precisely as possible to the exact needs of the case.

E. The extent of First Amendment protection for product performance claims as opposed to price information should be spelled out.

The Court's decisions in the commercial speech area have heretofore been limited to situations involving price information. Nevertheless, as stated in *Virginia, supra,* 425 U.S. at 765,

> Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

As this language indicates, there is no logical reason why information concerning the performance of the product should be any less protected than information concerning the price. Common sense tells us that unless the nature and performance of the product can be communicated, the free flow of price information will be of little value. Again appellant submits that this is especially true in a case where a federal policy in favor of disseminating the information has been enunciated.

3. Sections 26463 and 26465 constitute an invalid prior restraint on freedom of expression.

Sections 26463 and 26465 prohibit the manufacturer and the seller of a drug or device of the types described from making any statement, even if true, for the purpose of

inducing a sale thereof unless the department has first authorized the statement. This is a classic system of prior restraint of expression. In light of the *Virginia* case, it comes before the court with a heavy presumption against its constitutional validity. *Heller v. New York* (1973) 413 U.S. 483, 37 L.Ed.2d 745, 93 S.Ct. 2789; *Organization for a Better Austin v. Keefe* (1971) 402 U.S. 415, 29 L.Ed. 2d 1, 91 S.Ct. 1575.

The presumption may be overcome only where adequate safeguards against suppression of truthful information have been provided. Thus in *Poulos v. New Hampshire* (1953) 345 U.S. 395, 97 L.Ed. 1105, 73 S.Ct. 760, reh. den. 345 U.S. 978, 97 L.Ed. 1392, 73 S.Ct. 1119, an ordinance requiring a license to conduct religious services in a park was held valid because of the ready availability of judicial relief to test the reasons for refusal. But in *Freedman v. Maryland, supra,* the prior licensing of motion pictures was not allowed where the exhibitor was required to withhold showing the film until he had first obtained a judicial determination that it was not obscene with no assurance that such determination would be speedy. See also *Staub v. Baxley* (1958) 355 U.S. 313, 2 L.Ed.2d 302, 78 S.Ct. 277, and *Neimotko v. Maryland* (1951) 340 U.S. 268, 95 L.Ed. 267, 71 S.Ct. 325.

Here the California legislature has enacted a statute which imposes prior restraints on commercial speech and provides no safeguards at all against suppression of truthful information. A statute having this effect cannot be sustained.

(h and i) Opinions, Judgment, and Orders

In addition to the opinion of the Court of Appeal which is appended as Exhibit A, the opinion and judgment of the Superior Court are appended hereto as Exhibits B and C. The order of the Court of Appeal denying rehearing is appended hereto as Exhibit D and the order of the Supreme Court of California denying a hearing is appended hereto as Exhibit E.

A copy of the Notice of Appeal to this Court which was filed in the Court of Appeal is appended hereto as Exhibit F.

Respectfully submitted,

STANLEY WALSH,
JORDAN, WALSH, LAWRENCE,
DAWSON & CARBONE,
Attorneys for Appellants Dahlberg Electronics, Inc., and Detection Sciences, Inc.

(Exhibits Follow)

Exhibit A

CERTIFIED FOR PUBLICATION
In the Court of Appeal
State of California
First Appellate District,

Division Four

1 Civil No. 40017
(Sup.Ct.No. 51868)

George Kievlan, et al.,
Plaintiffs, Respondents and Appellants,
vs.
Dahlberg Electronics, a corporation, et al.,
Defendants, Appellants and Respondents.

[Filed Mar. 21, 1978]

OPINION

Dahlberg Electronics, Inc., and Detection Sciences, Inc., defendants, appellants and respondents,[1] appeal from a judgment[2] permanently enjoining them "from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and

[1]As both parties are appellants and respondents, for literary convenience we will refer to Dahlberg Electronics, Inc., and Detection Sciences, Inc., as defendants, and Kievlan and the other senior citizens as plaintiffs.

[2]The judgment was entered following plaintiffs' motion for summary judgment. The defendants agree there is no contested issue of fact in the case, only issues of law.

deafness." George Kievlan, et al., plaintiffs,[3] respondents and appellants, have appealed from the judgment on the ground that attorney's fees were not awarded.

Dahlberg Electronics, Inc., is a Minnesota corporation which manufactures "Miracle Ear" and "Magic Ear" hearing aids. Dahlberg is a wholly owned subsidiary of Detection Sciences, Inc., a Minnesota corporation. Dahlberg sells a substantial number of hearing aids in California through retail hearing aid dealers. Dahlberg advertises its hearing aids extensively in national publications. Other advertisements are distributed by Dahlberg to its local dealers.

Defendants have appealed from the judgment on the grounds (1) the trial court erred in its construction and application of section 26463 of the Health and Safety Code; (2) that the statute is unconstitutional; and (3) that state regulation of hearing aid advertising has been preempted by federal law and regulations.

Plaintiffs have appealed on the ground that the judgment did not award attorney's fees.

I

Defendants contend that the injunction does not merely prohibit advertising that their hearing aid would have a curative or therapeutic effect but that it also prohibits them from advertising that their hearing aids have *any effect*, including a compensatory effect on hearing loss. Defendants argue that section 26463 is concerned with false and misleading representations and that it is not the intent of the code section to prohibit advertising that a product will compensate for a physical disability without representing it will cure or remedy it. The difficulty with defendants' argument is that neither statute nor the judgment make any reference

[3]Plaintiffs allege that they are six senior citizens who have brought this suit on behalf of themselves and the general public.

to compensatory effect, so the argument is not relevant. The code section, 26463, subdivision (m), provides: "It is unlawful for any person to advertise any drug or device represented to have any effect in any of the folowing conditions, disorders, or diseases:

"...

"(m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness."

"The statute is clear and unambiguous and does not exempt any so-called 'compensatory effect.' There is an exception included in the Sherman Food, Drug and Cosmetics Law, which authorizes advertising of drugs and devices having a curative or therapeutic effect under certain conditions (§ 26465),[4] however, this section makes no mention of compensatory effect and there is no claim by defendants that they had received any such authorization from the department exempting their product."

Defendants also claim a hearing aid is not a "device" within the meaning of Health and Safety Code section 26009, which provides: " 'Device' means any instrument, apparatus, or contrivance, including any component part, product, or by-product of a device, or accessory, which is used, or intended for use, for any of the following:

"(a) In the diagnosis, cure, mitigation, treatment, or prevention of disease in man or any other animal.

[4]Section 26465 of the Health and Safety Code provides:

"Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health."

"(a) To affect the structure or any function of the body of man or any other animal." Without question, a hearing aid is an instrument or apparatus used in the *mitigation* of hearing diseases and affects the bodily functioning of the person using it. We also note that Business and Professions Code section 3305 defines a hearing aid as: "... any wearable instrument or device designed for, or offered for the purpose of, aiding or compensating for impaired human hearing."

Defendants contend that hearing aid dispensers are regulated by provisions of Division 2, chapter 7.5 (commencing with § 3300) of the Business and Professions Code. This chapter provides for the licensing of persons who engage in the practice of fitting and selling hearing aids. Defendants do not contend that they are licensed under this act. Furthermore, defendants cite no authority to support their positions that chapter 7.5 and the Sherman Act are mutually exclusive. They are in fact complimentary and in a proper case both can apply.

II

Defendants contend that section 26463 denies freedom of speech as guaranteed by the First Amendment of the United States Constitution, citing *Va. Pharmacy Bd. v. Va. Consumer Council* (1976) 425 U.S. 748. However, we need not reach this problem.

The judgment enjoined defendants from advertising their hearing aids by representing that the hearing aids have any effect on diseases or disorders of the ear including hearing loss and deafness. The Sherman Act, section 26460, declares it is unlawful for any person to disseminate any false advertisement of any device and declares an advertisement is false if it is false or misleading in any particular. It is clear from the copies of the advertisements that are included in the record that the advertisements were misleading in that

they convey the impression that the hearing aid would have a curative or therapeutic effect. The defendants in their brief concede that hearing aids do not have a curative or therapeutic effect. The *Virginia State Board of Pharmacy* case is of no help to defendants. As a concurring opinion points out the court's decision did not preclude state and federal regulation of false or deceptive advertising. The injunction is thus proper.

III

Defendants' third contention is that state regulation of hearing aid advertising has been preempted by federal law and regulation.[5] On May 28, 1976, the Medical Device Amendments of 1976 (90 Stat. 540) were enacted, amending the Federal Food, Drug and Cosmetics Act. (21 U.S.C., § 301 et seq.) As amended, section 360K of that act provides:

"(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

"(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

"(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

[5]This point was timely raised notwithstanding the fact that it was mentioned for the first time in defendants' closing brief. The implementing regulations were not approved until February 10, 1977, two months after defendants had filed their opening brief. Where a point of law which is determinative of an appeal is announced after the filing of the opening brief, the appellant is permitted to present the point in a closing or supplemental brief. (Meier v. Ross General Hospital (1968) 69 Cal.2d 430, 423-424, fn. 1.)

"Exempt Requirements

"(b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

"(1) the requirement is more stringent that a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

"(2) the requirement—

"(A) is required by compelling local conditions, and

"(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter. June 25, 1938, c. 675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574." Implementing regulations concerning hearing aid devices were approved by the Food and Drug Administration on February 10, 1977, and became effective August 15, 1977. (21 C.F.R., §§ 801.420, 801.421.) According to the language of section 360K, the preemptive effect of the act upon state action, with respect to hearing aids, is to be determined by the three-way test (1) whether the state action is a "requirement" and, if it is, (2) whether it is "different from, or in addition to" any requirement of the act on that subject *and* (3) whether it "relates to the . . . effectiveness" of hearing aids. (21 U.S.C., § 360K, subd. (a).) Because the three factors appear in a conjunctive context (see *ibid.*), all three must appear before a court may declare that the act preempts Health and Safety Code section 26463, subdivision (m), in the hearing aid business.

Section 26463, subdivision (m), meets the third test to the categorical extent that it "relates to the . . . effectiveness" of hearing aids by prohibiting representations on this subject in copy which advertises them for sale. But, because it does this and no more, it fails the first test of preemption because it is a flat *prohibition*: it is not a "requirement."

If it may be treated as a "requirement," its effect is nevertheless limited to the *advertising* of hearing aids for sale. The federal act reaches the subject of advertising, but of "restricted devices" only. (21 U.S.C., § 352, subd. (r).) By the act's terms, "restricted devices" are those which the Secretary of Health, Education and Welfare determines, by regulation, may be sold upon licenses-practitioner prescription only. (21 U.S.C., § 360j, subd. (e)(1). For congressional intent on this precise subject, see 1976 U.S. Code Cong. & Admin. News, No. 3, Medical Device Amendments of 1976 [commencing at p. 1070], pp. 1086, 1113-1114.)

Defendants have not shown that the secretary has classified hearing aids as "restricted devices." The federal act itself thus includes no "requirement" concerning the advertising of hearing aids. No such "requirement" appears in the implementing regulations adopted by the secretary, which have nothing to do with advertising. (See 21 C.F.R., §§ 801.420-801.421.) Health and Safety Code section 26463, subdivision (m), cannot be "different from, or in addition to," a "requirement" of the act which does not exist. The second test of its preemption by the act therefore fails as well. Thus, section 26463 is not preempted by federal law.

IV

Plaintiffs contend that the trial court erred in refusing to award them attorney's fees. They contend the trial court

had the power to award attorney's fees under three theories: (1) the "substantial benefit" rule, (2) the private attorney general concept, and (3) the newly enacted Code of Civil Procedure section 1021.5, which became effective January 1, 1978.

Applicability of each of these theories of recovery depends on the facts of the particular case. At the time this case was tried, August 1975, *Mandel v. Hodges* (1976) 54 Cal.App.3d 596, and *Serrano v. Priest* (1977) 20 Cal.3d 25, modified 20 Cal.3d 190a, had not been decided and Code of Civil Procedure section 1021.5 had not been enacted. Neither the trial court nor the attorneys had the benefit of these authorities before them and the court specifically based its ruling, denying attorney's fees, on the apparent state of the law at that time. The judgment must, therefore, be reversed as to the issue of attorney's fees and the matter remanded to the trial court on that issue for further proceedings.

Plaintiffs contend that Code of Civil Procedure section 1021.5 would not be applicable as it was not in effect at the time of trial. As stated in *Olson v. Hickman* (1972) 25 Cal. App.3d 920, 922: "Respondent . . . invokes the general rule of construction which frowns upon statutory retroactivity in the absence of a clear legislative direction. The rule has no application here. Section 800 [of the Government Code][6] classes itself as an ancillary provision, creating no new cause of action. It is procedural only. A lawsuit is governed by a change in procedural rules made during its pendency, and the suit is pending until its final determination on appeal." Section 1021.5 does not create a new cause of action; it is ancillary to the underlying cause. The cases cited by defendants are not in point, they involve changes that

[6]Government Code section 800 provides for the award of attorney's fees under certain circumstances in any civil action against a government agency or officer.

affect the cause of action. Section 1021.5 is not rendered inapplicable to the present case solely because of its effective date.

The judgment is reversed insofar as it does not provide for attorney's fees and the cause is remanded to the trial court for further proceedings on this issue only. In all other respects the judgment is affirmed. Plaintiffs to recover costs on appeal.

CERTIFIED FOR PUBLICATION

Caldecott, P. J.

We concur:

Rattigan, J.

Ragan, J.*

*Assigned by the Chairperson of the Judicial Council.

Exhibit B

Superior Court of the State of California
for the County of Santa Cruz

No. 51868

George Kievlan, et al.,
Plaintiffs,

vs.

John Maier, et al.,
Defendants.

[Filed Aug. 21, 1975]

OPINION

This is an action brought by six senior citizens on behalf of themselves and as private attorneys general against Dahlberg Electronics, a manufacturer of hearing aid devices, and against local dispensers of those devices. The plaintiffs' claims for damages against the dispensers have been settled. By this motion for summary judgment, the Court is asked to determine the last remaining issue; namely, the legality of the manufacturer's advertisements of its hearing aids. The defense agrees that there are no contested issues of fact so that the remedy of summary judgment is proper.

The Law.

Plaintiffs' case is based on Health & Safety Code § 26463(m) which provides as follows:

> "It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

. . . (m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness.

Also relevant are the following sections:

"§ 26464. An advertisement which is not unlawful under § 26460 [false advertising] is not unlawful under § 26463 if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices."

"§ 26465. Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in § 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health."

"§ 26009. *Device.* "Device" means any instrument, apparatus, or contrivance, including any component, part, product, or by-product of a device, or accessory, which is used, or intended for use, for any of the following:

(a) In the diagnosis, cure, mitigation, treatment, or prevention of disease in man or any other animal.

(b) To affect the structure of any function of the body of man or any other animal."

The Advertisements.

Dahlberg Electronics advertises its hearing aids extensively in national publications. One ad in comic strip form is correctly described in plaintiff's brief as follows:

". . . it depicts the story of a mother who cannot understand the words at her daughter's graduation. Her doctor has told her she has mild nerve deafness, but he can not help her. She then reads a circular which implies that Dahlberg Hearing Aids can help mild nerve deafness. Visiting a Dahlberg dealer, her husband queries if anything can be done about her going deaf. The dealer tells her that 'medical experts generally agree that no effective cure has yet been found for this type of hearing loss.' She responds in despair, 'You mean it's hopeless?' Smiling, the dealer answers, 'It might have been different years ago, Mrs. Goodwin. But now, fortunately, modern science has created a tiny new electronic device made to help in most cases like yours . . .' The story then goes on to show how for the first time in years she can understand words clearly because of her Dahlberg Miracle Ear hearing aid. The reader is asked to send in a postcard which will tell her (or him) 'How I may be able to hear again more clearly in both ears without using hearing aids that have cords or tubes."

Other advertisements stress that Dahlberg's "Miracle Ear" hearing aid is designed for those who suffer from nerve impairment or mild nerve deafness and that the device will allow the wearer to hear more clearly.

The advertising campaign has been effective. Between January 1, 1972 and February 14, 1973, 11,903 postcard responses were received by Dahlberg from California residents who were then referred to local Dahlberg dealers.

Plaintiffs' Contention.

Plaintiffs' position can be stated in the form of a syllogism:

1. The statute prohibits the advertising of a device represented to have any effect on disorders of the ear including hearing loss.

2. Defendant's advertising claims effectiveness to compensate for hearing loss in cases of nerve impairment or nerve deafness.

3. Therefore, the statute prohibits advertising such as defendant's.

Defendant's Contention.

It is the defendant's basic position that § 26463 prohibits only the claim that the product or device has therapeutic or curative effect as distinguished from the assertion of a claim that the device merely compensates for the disorder or condition the way a prosthesis does for loss of a limb. This argument is drawn primarily from § 26465 which provides that if the Department of Health determines a type of self-medication to be medically safe for any of the conditions listed in § 26463, it may authorize the advertisement of the drug or device "as having a curative or therapeutic effect . . ."

The defendant's contention is not persuasive.

One. The language of § 26463 is sweeping; it prohibits the advertising of a device represented to have *any* effect. The use of the word "any" in a statute negatives the suggestion that the law was to be given a restrictive interpretation. *Emmolo v. So. Pacific,* 91 C.A.2d 87 (1949); *In Re Wymans Estate,* 208 C.A.2d 489 (1962).

Two. Granting that § 26463 and § 26465 have to be construed together, defendant is not aided. The words "curative" and "therapeutic" are used in the disjunctive in § 26465. Each has its distinctive meaning; therapy is obviously a far broader and more generic concept than cure. Products or devices which compensate for a loss accomplish a therapeutic purpose, as that term is ordinarily understood. A thyroid pill compensates for thyroid

deficiency; taking such medication does not cure such disorder but it has the therapeutic effect of permitting a person suffering from that condition to lead a normal life. The same can be said of insulin, crutches, prostheses and hearing aids.

Three. That § 26463 should be given a broad construction is also apparent from the legislative policy underlying the Pure Drugs Act. Basically the purpose of that legislation was to (1) encourage the general public to seek professional care for the conditions listed; and (2) prevent the commercial exploitation of the general public by the advertising of drugs or devices which may be useful but whose efficacy in particular cases cannot be determined by laymen. § 26464, § 26465; *People v. Ryan,* 101 C.A.2d 927, 931 to 932 (1951). Those policy considerations clearly apply to hearing aids, devices which help some persons suffering from impaired hearing and do not help others. As people with hearing defects desperately want help, they are especially suggestible. Finally, the devices are expensive; and they are needed primarily by the elderly, a class traditionally the objects of legislative solicitude and entitled to it.

Attorney's Fees.

Plaintiffs seek attorney's fees because they brought this action as private attorneys general; they claim that their efforts culminated in a decision yielding substantial benefits to a broad class of citizens. The doctrine authorizing the award of attorney's fees under those circumstances is entirely the creature of the federal courts, as the California Supreme Court has pointed out. *D'Amico v. Board of Medical Examiners,* 11 C.3d 1, 27 (1974). Now that the U. S. Supreme Court has overruled those decisions of the lower federal courts, the legal foundation for such an award has been removed. *Aleyska Pipe Line Serv. v. Wild-*

erness Soc., ... U.S. ....., 44 L.Ed.2d 141, 161, footnote 46 (1975).

An injunction will issue restraining defendant Dahlberg from making any performance claim in the advertising of its hearing aids. Nothing contained herein precludes defendant from advertising its places of business, that Dahlberg hearing aids are sold there, the prices of the instruments or any other information of that nature.

Dated: August 21, 1975.

HARRY F. BRAUER
Judge of the Superior Court

Exhibit C

Superior Court of the State of California
for the County of Santa Cruz

No. 51868

George Kievlan, Eris Gofinch, Charles Harrold, Mary Walker, Gladys Faustine, Minnie Carp, individually, and on behalf of the general public,
Plaintiffs,
vs.
John Maier, L. A. Stacey, Professional Hearing Aid Center, an individual Proprietorship; Dahlberg Electronics, a Corporation; Detection Science, a Corporation; and Doe 1 through Doe 20,
Defendants.

[Filed Mar. 22, 1976]

JUDGMENT

The above-entitled cause came on pursuant to Plaintiffs' Motion for Summary Judgment on August 13, 1975, in Department III of the above-entitled Court, the Honorable Harry F. Brauer, Judge presiding. Plaintiffs appeared by James Rumble, Diane Greenberg and Richard Pearl, their attorneys, and Defendants Dahlberg Electronics, Inc. and Detection Sciences, Inc., appeared by their attorneys, Thomas F. Nelson and Fred Hollander.

Said cause having been heard, documentary evidence presented by both plaintiffs and defendants having been received and admitted without objection, the Court having rendered its decision in favor of plaintiffs and against

defendants, as reflected in its opinion of August 21, 1975, the Court having caused to be made and filed its written Findings of Fact and Conclusions of Law.

It Is Ordered, Adjudged And Decreed that Plaintiffs George Kievlan, Eris Gofinch, Charles Harrold, Mary Walker, and Gladys Faustine have judgment against Defendants Dahlberg Electronics, Inc. and Detection Sciences, Inc. and that Defendants be and they hereby are permanently enjoined and restrained from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and deafness.

Dated: March 17, 1976

HARRY F. BRAUER
Judge of the Superior Court

Judgment entered on March 22, 1976, in Judgment Book, Vol. 148, page 320.

RICHARD C. NEAL
Clerk

By: JOAQUINA AZEVEDO
Deputy

Approved as to Form:

By: /s/ THOMAS F. NELSON
Attorney for Defendants

Exhibit D

In the Court of Appeal
State of California

First Appellate District

Division Four

No. 40017

George Kievlan, et al.,
Plaintiffs, Respondents and Appellants,
vs.
Dahlberg Electronics, Inc., et al.,
Defendants, Appellants and Respondents.

BY THE COURT:

The petition for a rehearing filed in the above entitled cause is hereby denied.

Dated: April 14, 1978

Caldecott, P.J.

Exhibit E

Order Due
June 19, 1978

In the Supreme Court
of the State of California
In Bank

Kievlan et al
Plaintiffs and Appellants

v.

Dahlberg Electronics et al
Defendants and Appellants

Bird, C.J., did not participate.

[Filed Jun 15, 1978]

ORDER DENYING HEARING
After Judgment by the Court of Appeal
1st District, Division 4, Civil No. 40017

Defendant's petition for hearing DENIED.

Manuel, J., is of the opinion that the petition should be granted.

TOBRINER
Acting Chief Justice

Exhibit F

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In the Court of Appeal
State of California

First Appellate District

Division Four

1 Civil No. 40, 017

George Kievlan, et al.,
Appellees,

vs.

Dahlberg Electronics, Inc., et al.,
Appellants.

[Filed Sep. 1, 1978]

NOTICE OF APPEAL TO THE SUPREME COURT
OF THE UNITED STATES

To the Clerk of the Above Entitled Court:

Notice Is Hereby Given that Dahlberg Electronics, Inc. and Detection Sciences, Inc., the appellants above-named, hereby appeal from the final Judgment of the Court of

Appeal of the State of California, affirming the Judgment of the Superior Court of the State of California, entered in this action on March 21, 1978, and which became final on June 15, 1978.

This appeal is taken pursuant to 28 U.S.C. § 1257(2).

Dated: August 31, 1978.

Stanley Walsh
David P. Dawson
Michael P. Carbone
Jordan, Walsh, Lawrence, Dawson & Carbone

By /s/ MICHAEL P. CARBONE
Attorneys for Appellants

(Proof of Service omitted)

Supreme Court, U. S.
FILED
NOV 1 1978
MICHAEL RODAK, JR., CLERK

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

vs.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants.

On Appeal from the Court of Appeal of the State of California First Appellate District

MOTION TO DISMISS OR AFFIRM

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In the Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

VS.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants.

On Appeal from the Court of Appeal
of the State of California
First Appellate District

MOTION TO DISMISS OR AFFIRM

Appellees respectfully move to dismiss the appeal filed herein, or in the alternative to affirm the judgment of the Court of Appeal of the State of California, First Appellate District. Rule 16(b) and (d).

(a) THE NATURE OF THE PROCEEDINGS

This lawsuit was brought by six elderly persons against one of the nation's largest manufacturers of hearing aids, Dahlberg Electronics, Inc., its parent company, Detection

Sciences, Inc. and a local hearing aid dealer who sold Dahlberg hearing aids.[1]

In addition to individual claims for rescission and damages based on fraud and misrepresentation by the local dealer, plaintiffs sought an injunction against Dahlberg's hearing aid advertisements. These advertisements proclaimed that Dahlberg hearing aids would benefit persons with hearing loss caused by nerve deafness or nerve impairment and requested interested persons to write to Dahlberg for more information.[2] Plaintiffs alleged that such advertisements violated California Health and Safety Code section 26463(m), which prohibits advertising of medical devices represented to have any effect on "diseases or disorders of the ear and auditory apparatus, including hearing loss and deafness". The injunction was sought on behalf of the general public pursuant to California Civil Code section 3369.[3]

Plaintiffs' claims against the local hearing aid dealer were settled prior to trial. The individual plaintiffs' purchases of unneeded hearings aids were rescinded, and in addition, five of the plaintiffs received punitive damages of seven hundred dollars ($700.00) each.

On plaintiffs' injunction claim, the superior court ruled that Dahlberg had violated section 26463(m), and that although it could continue to advertise "its place of business, that Dahlberg hearing aids are sold there, the prices of the instruments or any other information of that nature", it would be enjoined from representing that its hearing aids "have any effect on diseases or disorders of the ear, including hearing loss and deafness".

[1]For convenience, appellants Dahlberg Electronics, Inc. and Detection Sciences, Inc. will be collectively referred to as "Appellant" or "Dahlberg" in this Brief.

[2]Copies of the advertisements in question are appended hereto as Exhibit 1.

[3]California Civil Code Section 3369 read, in relevant part:

". . .

2. Any person performing or proposing to perform an act of unfair competition within this State may be enjoined in any court of competent jurisdiction.

. . .

5. Actions for injunction under this section may be prosecuted by the Attorney General or any district attorney in this State in the name of the people of the State of California upon their own complaint or upon the complaint of any board, officer, person, corporation or association or by any person acting for the interests of itself, its members or the general public."

(b) STATUTES INVOLVED.

This appeal involves California Health and Safety Code section 26463, which is part of California's Sherman Food, Drug, and Cosmetic law (California Health & Saf. Code, div. 21). Section 26463 is part of the chapter of the Sherman Act dealing with "Advertising" (Ch. 4, art. 3); it reads:

> "It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:
>
> (a) Appendicitis.
> (b) Blood disorders.
> (c) Bone or joint diseases.
> (d) Kidney disease or disorders.
> (e) Cancer.
> (f) Carbuncles.
> (g) Disease, disorder or condition of the eye.
> (h) Diabetes.
> (i) Diphtheria.

(j) Gall bladder disease or disorder.

(k) Heart and vascular diseases.

(l) High blood pressure.

(m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness.

(n) Measles.

(o) Meningitis.

(p) Mental disease or mental retardation.

(q) Paralysis.

(r) Pneumonia.

(s) Poliomyelitis.

(t) Prostate gland disorders.

(u) Conditions of the scalp, affecting hair loss, or baldness.

(v) Alcoholism.

(w) Peridontal diseases.

(x) Epilepsy.

(y) Goiter.

(z) Endocrine disorders.

(aa) Sexual impotence.

(ab) Sinus infection.

(ac) Encephalitis.

(ad) Tumors.

(ae) Venereal disease.

(af) Tuberculosis.

(ag) Ulcers of the stomach.

(ah) Varicose ulcers.

(ai) Scarlet fever.

(aj) Typhoid fever.

(ak) Whooping cough."

Two other sections relevant here are California Health and Safety Code sections 26464 and 26465. Section 26464 states:

> "An advertisement which is not unlawful under Section 26460 is not unlawful under Section 26463 if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices."

Section 26465 reads:

> "Whenever the [California Department of Health] determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health."

(c) QUESTIONS PRESENTED.

I. Whether the court below was correct in holding that California Health and Safety Code section 26463(m) has not been preempted by the F.D.A. hearing aid regulations promulgated pursuant to the Medical Device Amendments of 1976?

II. Whether the court below was correct in holding that Health and Safety Code section 26463(m) and the injunction issued pursuant to it do not infringe upon appellant's constitutional right to free speech?

(d) STATEMENT OF THE CASE.

On August 13, 1975, the Superior Court of Santa Cruz County, Judge Harry F. Brauer, heard Plaintiffs' Motion for Summary Judgment, in which Plaintiffs sought an injunction barring Dahlberg from continuing to advertise its hearing aids in violation of California Health and Safety Code section 26463(m). In support of their claim, plaintiffs presented the following facts about Dahlberg's advertisements to the superior court:

1. Copies of four advertisements used to promote Dahlberg hearing aids were submitted. (C.T. 200-203).[4] Two of the advertisements were those Dahlberg stated were the advertisements that it ran in several magazines of national circulation (C.T. 206) (Ex. 1, pp. 1-3); The other two ads were run by the local dealer. (Ex. 1, pp. 4-5).

2. The advertisements solicited responses from persons with hearing problems, and provided a form for them to fill out and mail to Dahlberg. These forms were then sent by Dahlberg to local Dahlberg dealers, who used these "leads" to sell hearing aids by making personal visits to the homes of the persons who had responded. (C.T. 208-212).

3. Dahlberg's advertisements produced 11,903 postcard responses from Californians during the period between January 1, 1972 and February 14, 1973. (C.T. 213).

The plaintiffs also presented facts demonstrating the harm caused by such advertisements. These included serious and repeated incidents of abusive sales practices used by

[4]See Exhibit 1.

the local Dahlberg dealer, resulting in the plaintiffs being sold expensive hearing aids which could not or did not help them, and which in several cases were not medically appropriate. (C.T. 32-91).

Evidence of a widespread pattern of similar abuses in the hearing aid industry generally was demonstrated by *A Report On Hearing Aid Health Care* (September, 1974), prepared by an inter-departmental task force created by the United States Department of Health, Education and Welfare to study hearing aid health care issues.[5] (C.T. 124-194). That report concluded that the medical problems of thousands of persons go undiagnosed because most persons with hearing problems go to a hearing aid dealer before they go to a physician or audiologist. The report also concluded that many persons are sold hearing aids who cannot be helped by them, and many others are sold the wrong type of hearing aid. The report also found that misleading advertising and high pressure sales were prevalent in the hearing aid industry, and that hearing aids were being sold at excessively high prices, especially to the elderly.

In its response (C.T. 235-275), the appellant did not dispute any of these facts and produced no counter-evidence on any of the factual issues, although it was its duty to do so under California law. California Code of Civil Procedure § 437c; California Evidence Code § 455; *see, Cornelison v. Kornbouth,* 15 Cal.3d 590, 595-596, 125 Cal.Rptr. 557 (1975).

[5]This report, as subsequently modified, formed the basis for the Food and Drug Administration's regulations on hearing aids, discussed in greater detail *infra* at pp. 12-30. 41 Fed.Reg. 16756 (April 21, 1976).

The appellant offered only two defenses to plaintiffs' motion:

1. That section 26463(m) was applicable only to advertisements claiming hearing aids would have a "curative or therapeutic" effect, and that Dahlberg's advertisements were not within its scope because they represented hearing aids would have a "compensatory" effect;

2. That bills amending Health and Safety Code section 26463(m) were before the California Legislature, and therefore the court should not decide the issue until that legislation had been passed or defeated.[6]

The appellant did *not* raise the argument that the statute violated its First Amendment right to freedom of speech.

Based on this evidence and the arguments presented by the parties, the trial court issued an opinion sustaining plaintiffs' claim. (Appellant's Jurisdictional Statement hereinafter "J.S.", Ex. B). It found, *inter alia,* that Dahlberg's hearing aid advertisements were both "extensive" and "effective".

1. "Dahlberg Electronics advertises its hearing aids extensively in national publications." (C.T. 301).

2. "Other advertisements are distributed by Dahlberg to its local dealers . . . ." (C.T. 302).

3. "These advertisements stress that Dahlberg's 'Miracle Ear' hearing aid is designed for those who suffer from nerve impairment or mild nerve deafness and that the device will allow the wearer to hear more clearly." (C.T. 302).

[6]Those bills subsequently were defeated.

4. "Dahlberg's advertising campaign has been effective." (C.T. 302).

5. "Between January 1, 1972 and February 14, 1973, 11,903 postcard responses [to Dahlberg's advertisements] were received by Dahlberg from California residents, who were then referred to local Dahlberg dealers." (C.T. 302).

The court also found that because of these advertisements, the plaintiffs and the public in general were being irreparably harmed:

6. "Defendant Dahlberg's advertisements have the tendency and capacity to injure many people who are hard of hearing and who read said advertisements." (C.T. 303).

7. "These people rely to their detriment on the defendant's representation that Dahlberg hearing aids will help them." (C.T. 303).

8. "The injuries they suffer include buying unnecessary hearing aids and foregoing necessary diagnosis and treatment." (C.T. 303).

The court examined these facts in light of the purposes of the statute:

> "That § 26463 should be given a broad construction is also apparent from the legislative policy underlying the Pure Drugs Act. Basically the purpose of that legislation was to (1) encourage the general public to seek professional care for the conditions listed; and (2) prevent the commercial exploitation of the general public by the advertising of drugs or devices which may be useful but whose efficacy in particular cases cannot be determined by laymen. § 26464, § 26465; *People v. Ryan,* 101 C.A.2d 927, 931 to 932 (1951)." (J.S. at 41).

It then found that these purposes were directly applicable to hearing aid advertisements:

> "Those policy considerations clearly apply to hearing aids, devices which help some persons suffering from impaired hearing and do not help others. As people with hearing defects desperately want help, they are especially suggestible. Finally, the devices are expensive; and they are needed primarily by the elderly, a class traditionally the objects of legislative solicitude and entitled to it." *(Ibid).*

It concluded by enjoining appellant's advertisements, in language that tracks the language of section 26463(m):

> "Defendants . . . are permanently enjoined and restrained from advertising their hearing aids in California by representing that said hearing aids have any effect on disease or disorders of the ear, or auditory apparatus, including hearing loss and deafness." (*Id.* at 44).

However, the court explicitly qualified the injunction by noting:

> "The use of the term hearing aid in and of itself is not a violation of Section 26463(m), and nothing contained herein preludes defendants or their dealers from advertising their place of business, that Dahlberg hearing aids are sold there, the prices of their hearing aids, or any other information of that nature." (*Id.* at 42).

On appeal to the California District Court of Appeal, the appellant contested the merits of the trial court's interpretation of Health and Safety Code section 26463(m). In addition, for the first time, it raised the issues of whether the statute violated the First Amendment and whether it had been preempted under federal law.

The decision of the court of appeal (J.S., Ex. A) affirmed the judgment of the trial court. First, the appellate court found that the appellant's attempt to construe the statute to exclude advertisements representing "compensatory" effects was contrary to the express language of the statute, and that the statute prohibited advertisements representing hearing aids to have "any effect" on hearing loss or deafness. (*Id.* at 30).

On the First Amendment issue, the court specifically declined to reach the merits of appellant's claim because it found that the advertisements were misleading, and therefore beyond the scope of any First Amendment protection; the court said:

> "It is clear from the copies of the advertisements that are included in the record that the advertisements were misleading in that they convey the impression that the hearing aid would have a curative or therapeutic effect." (*Id.* at 31-32).

Finally, on the preemption issue, the court found that the statute was not preempted by federal law because it did not impose a "requirement" relating to the safety and effectiveness of hearing aids, and because even if it was a requirement, it was not different from or in addition to any requirement under the federal regulations. (*Id.* at 32-34).[7]

Appellant's Petition for Hearing by the California Supreme Court was denied on June 15, 1978. (J.S., Ex. E).

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[7]At this point, it should be noted that the California Department of Health, the state agency responsible for enforcing section 26463, filed an *amicus curiae brief* on behalf of the plaintiffs in the court of appeal opposing both Dahlberg's statutory interpretation and preemption arguments.

(e) THE CASE PRESENTS NO SUBSTANTIAL FEDERAL QUESTION.

I. California Health And Safety Code Section 26463(m) Has Not Been Preempted By The F.D.A. Hearing Aid Regulations Promulgated Pursuant to The Medical Device Amendments Of 1976.

Appellant claims that the court below erred in rejecting its contentions that California Health and Safety code section 26463(m) was preempted by the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301, *et seq.*, as amended by the Medical Device Amendments of 1976, Pub.L. 94-295, 90 Stat. 539) and the hearing aid regulations promulgated under it by the Food and Drug Administration (hereinafter "F.D.A.") (21 C.F.R. §§ 801.420 and 801.421 (42 Fed.Reg. 9286 (February 15, 1977))). As we will show, however, the issue should not be resolved judicially at this time. Moreover, the lower court's decision is fully supported by the language and purposes of the federal Act, by the F.D.A.'s regulations and interpretations of the Act, and by the decisions of every court that has considered the question.

A. Under The Primary Jurisdiction Doctrine, This Court Should Not Assume Jurisdiction To Consider The Preemption Issue Raised By Appellant Because That Issue, Pursuant To Congress' Directive, Is Currently Pending Before The Food And Drug Administration.

1. Pursuant To The Procedure Established In The Medical Device Amendments Of 1976, The F.D.A. Has Preliminarily Ruled That Section 26463(m) Is Either Not Preempted Or Is Exempt From Preemption.

The Medical Device Amendments of 1976 were enacted to provide the Food and Drug Administration with broader authority to regulate the safety and effectiveness of medical devices. While Congress envisioned that federal regulation would be preeminent in the area, it did not intend federal law to preempt all state regulation of medical devices. Instead, in section 521 of the Act (21 U.S.C. § 360K), it carefully established standards for when state regulation of medical devices should be preempted. Under section 521, state laws were only to be preempted if all the conditions set forth in section 521(a) of the Act were met. Section 521(a) reads:

> "Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, **and**
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Even where it is shown that all these prerequisites have been met, however, preemption is not always required. Section 521(b) of the Act (21 U.S.C. § 360K(b)) allows the F.D.A. to exempt from preemption state laws that are more stringent than the federal requirements; it reads:

> "Upon application of a state or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a

requirement of such state or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

In response to the federal statute, the California Department of Health submitted an application requesting, *inter alia,* that to the extent California's Sherman Act provisions applicable to medical devices might be preempted, that they be exempted from preemption because they were more stringent than the federal requirements.

In response to that application, on February 15, 1977, the F.D.A. issued a proposed regulation (Proposed 21 C.F.R. § 808.55) granting California's application for exemption (42 Fed.Reg. 9186).[8] The proposed regulation reads, in relevant part:

"(a) The following California medical device requirements are enforceable notwithstanding section 521 of the Federal Food, Drug and Cosmetic Act, either because they are not preempted by section 521(a) or because the Commissioner of Food and Drugs has

[8]In the proposed regulation, the F.D.A. found that only one California statute (Business and Professions Code § 2541.3, dealing with opthalmic devices) had been preempted by the federal Act. 42 Fed. Reg. 9189.

granted an exemption from preemption pursuant to section 521(b) of the act:

"(1) Sherman Food, Drug, and Cosmetic Law (Division 21, Health and Safety Code)."

Since Division 21 of the Sherman Food, Drug, and Cosmetic Law includes Health and Safety Code section 26463(m), the F.D.A. clearly did not intend to preempt the statute at issue here.[9]

On the same day, February 15, 1977, the F.D.A. published final regulations (effective August 15, 1977) setting out requirements for labeling hearing aids; the purpose and scope of these regulations specifically did not include regulation of hearing aid advertising:

"The Food and Drug Administration (FDA) is establishing uniform professional and patient *labeling* requirements and conditions for sale of hearing aid devices. The regulations prescribe the *types of information that must be included in the labeling* to provide hearing professionals and patients with adequate directions for the safe and effective use of a hearing aid; specify the technical performance data that must be included in the *labeling* to ensure that hearing health professionals have adequate information to select, fit, and repair a hearing aid for a patient; and restrict the sale of a hearing aid to those patients who have undergone medical evaluation within the past 6 months, but with a provision that fully informed adult patients (18 years of age or older) may waive the medical evaluation because of personal or religious beliefs." (42 Fed.Reg. 9286) (Emphasis added).

[9]Proposed section 808.55(a)(1) is still pending before the F.D.A.

Indeed, the F.D.A. noted that regulation of hearing aid sales practices, including advertising, were not within the scope of its authority but would be left to the Federal Trade Commission (hereinafter "F.T.C."). 42 Fed.Reg. at 9286.

On May 2, 1978, the F.D.A. published final regulations establishing detailed standards and procedures for considering applications for exemptions from the federal Act. 21 C.F.R. §§ 808.1-.35. 43 Fed.Reg. 18661 *et seq.* Those regulations established that under section 521(a) of the Act, state laws would be preempted only when the F.D.A. had established "specific counterpart regulations" applicable to the device. 21 C.F.R. § 808.1(d).[10]

Finally, and of critical importance to the instant case, on July 26, 1978, the F.D.A. published proposed regulations granting the applications for exemptions of state hearing aid requirements from preemption submitted by several states, including California. Under these proposed regulations, the F.D.A. has specifically ruled that California Health and Safety Code section 26463(m) is *not* preempted by federal law; the F.D.A. states:

> "The Commissioner is also proposing to exempt from preemption California's Health and Safety Code, section 26463(m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521(a) of the act." (43 Fed.Reg. 33182).

[10]Section 808.1(d) reads, in relevant part:

"(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements."

Thus, the precise question appellant raises is currently being considered in the forum Congress explicitly intended it be determined—the Food and Drug Administration. As we will explain in the next section, given the pendency of the F.D.A.'s regulations, a determination of the preemption issue by this Court at this time would run directly contrary to this Court's "primary jurisdiction" doctrine.

2. The F.D.A. Has Primary Jurisdiction Over The Preemption Issue Raised By Appellant, And Resolution Of That Issue By This Court Is Premature And Unnecessary.

The primary jurisdiction doctrine recognizes that where, as here, Congress has looked to the agency with expertise in the field to determine the scope or application of federal law, deference to the administrative agency is appropriate. In *Far East Conference v. U.S.*, 342 U.S. 570, 574 (1952), this Court said:

> "The Court thus applied a principle, now firmly established, that in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion,

agencies created by Congress for regulating the subject matter should not be passed over."[11]

In the instant case, the F.D.A. has great expertise in the regulation of medical devices and public health matters generally. Since the preemption issue raised by appellant is currently being considered by the F.D.A., a judicial determination prior to an administrative determination would be a particularly inefficient use of judicial resources.

Furthermore, there would be no prejudice to appellant from dismissal of its appeal in light of the F.D.A. proceedings. Should the F.D.A. reverse its proposed determination and decide that Health and Safety Code § 26463(m) is preempted, then, under the California Superior Court's inherent power to vacate prohibitory injunctions upon a showing of a change in the law, appellant can have the superior court's injunction dissolved.[12]

On the other hand, should the F.D.A. finalize its proposed regulation and decide that the statute is not preempted or is exempt from preemption, then appellant may seek judicial review of that order in a separate action. 5 U.S.C. § 702.

Thus, given the F.D.A.'s primary jurisdiction, and the remedies available to appellant from that decision, no substantial preemption question is properly before this Court at this time. *See, Far East Conference v. U.S., supra,* 342 U.S. at 495-496; *see also, U.S. v. Michigan National Corp.,* 419 U.S. 1 (1974) (per curiam).

[11]On the doctrine of primary jurisdiction generally, see 3, K. Davis, *Administrative Law Treatise,* Ch. 19.

[12]*Sontag Chain Stores Co. v. Superior Court,* 18 Cal.2d 92, 94-95, 113 P.2d 689 (1941); *cf., New Jersey Guild of Hearing Aid Dispensers v. Long,* 75 N.J. 544, 384 A.2d 795, 814 (1978).

B. Section 26463(m) Complements The Purposes Of The Federal Act And Regulations, And Thus Under Section 521 Of The Act Is Either Not Preempted Or Is Exempt From Preemption.

Although appellees respectfully submit that determination of the preemption issue raised by appellant is unnecessary, it is also clear that, on the merits, no substantial preemption question is presented.

Questions of preemption are basically questions of federalism. *Jones v. Rath Packing Co.,* 430 U.S. 519, 525 (1977). Thus, the extent of the state's prior involvement in the regulated field is a critical factor. If the area is one traditionally regulated by the states, then there is a presumption against federal preemption which only can be overcome by showing a "clear and manifest" intent by Congress to preempt state regulation. *Ibid; see also, New Jersey Guild of Hearing Aid Dispensers v. Long,* 75 N.J. 544, 384 A.2d 795, 808 (1978).

California has long regulated medical drug and device advertising under its plenary power to protect the public welfare.[13] Appellant, however, has entirely failed to show that the presumption against preemption that results from California's historical involvement in regulating medical device advertising has been overcome by a "clear and manifest" congressional intent to preempt California law. The reason for this failure is apparent—no such intent exists. An examination of the federal scheme reveals that the federal Act and regulations are concerned with an entirely dif-

[13]*See, e.g., Neslen v. Board of Health,* 70 Cal.App.2d 202, 160 P.2d 862 (1945); *California Cancer Quack Laws: The Best Is None Too Good,* 40 So.Cal. L.Rev. 384 (1967).

ferent aspect of the hearing aid industry than is addressed by section 26463(m), and thus there was no intent by Congress either explicitly or implicitly to preempt California's Sherman Act provisions for the regulation of hearing aid advertising.

1. There Is No Counterpart Federal Regulation To Section 26463(m) Because The Federal Act And Regulations Are Primarily Concerned With The Safety And Effectiveness Of Hearing Aids, Not Sales Practices Like Advertising.

California's regulation of hearing aid advertising is not explicitly preempted under section 521(a) of the Federal Food and Drug Act because section 26463(m) is not "different from, or in addition to any requirement" under the Act or F.D.A. regulations. 21 U.S.C. § 360K(a)(1). As the court of appeal found, the federal "requirements" deal only tangentially with the subject of advertising. (J.S. at 34). As noted previously, the primary concern of the F.D.A.'s regulations is labeling, not advertising;[14] in fact, the F.D.A. regulations totally ignore the field of hearing aid advertising. Thus, in the absence of "any specific counterpart regulations" (21 C.F.R. § 808.1(d)), there is no federal requirement which the statute can be "different from, or in addition to".[15]

[14]The critical difference between labeling and advertising is that while the former is objective and informational, the latter involves an intent to induce the purchase of the device. Compare California Health and Safety Code sections 26016 (defining "label") and 26002 ("advertisement").

[15]*See, Ray v. Atlantic Richfield Co.,* U.S. , 98 S.Ct. 988, 1001 (1978) (although federal agency could have enacted regulations preempting state law, in absence of any specific regulations on subject, state law not preempted.)

The court below is not alone in recognizing the difference between regulating hearing aids as devices and regulating hearing aid sales practices. In *New Jersey Guild of Hearing Aid Dispensers v. Long,* 75 N.J. 544, 384 A.2d 795 (1978), the Supreme Court of New Jersey held that New Jersey's laws regulating hearing aid sales practices were not preempted by the federal Act and F.D.A. regulations. The essence of the court's holding was that hearing aid sales practices were not within the scope of section 521(a) of the federal Act:

> "Key aspects of dispensing sales practices covered by the [state] regulations are left largely unregulated by the F.D.A. hearing aid regulations, which relate predominantly to requirements of labeling and conditions of sale." (384 A.2d at 811).

The court thus held that New Jersey regulations prohibiting door-to-door canvassing, banning misleading professional titles and regulating other sales practices were not preempted by federal law.

In *New York State Hearing Aid Society v. New York,* Civ. No. 76-C-1565 (E.D. N.Y. March 10, 1978),[16] the court held that New York's statutes regulating the sales practices of hearing aid dealers were not preempted by the F.D.A. regulations:

> *"The federal regulations are aimed at the safety and effectiveness of devices, not the manner in which they are sold.* Thus, while the state statute may not, absent exemptions, regulate guarantees and receipts in the face of superceding federal regulations, neither the supremacy clause of the Constitution nor Section 360k

[16]A copy of the district court's Memorandum and Order is appended hereto as Exhibit 2.

> of Title 21 prohibits the state from controlling who sells a hearing aid device *or the manner in which it is sold.*" (Ex. 2, p. 6) (Emphasis added).

The court went on to specify that New York laws prohibiting door-to-door canvassing and false, misleading, deceptive, or untruthful advertising were specifically *not* within the realm of the federal regulations, and therefore, not preempted. (Ex. 2, pp. 6-7).

Both the New Jersey and New York courts made essentially the same finding as the court of appeal in this case—that the federal regulations are concerned with the safety and effectiveness of the device itself and with the labeling that goes with the device, not with the sales practices and advertisements used to promote the device. Since that aspect of regulation of the hearing aid industry is left to the states, it is not preempted by federal law.

Thus, as the court of appeal correctly found, Health and Safety Code section 26463(m) is not a "requirement" within the meaning of section 521(a). It does not require hearing aid advertisers to do or say anything. Its only effect is to prohibit representations which have not been medically verified by the State Department of Health. Unlike the labeling requirements in *Jones v. Rath Packing Co., supra,* referred to by appellant, it does not "require" a different kind of information than the federal agency, and thus does not create an inevitable conflict. Furthermore, any information the F.D.A. might require would be allowed under state law pursuant to Health and Safety Code section 26465.

Appellant also refers to 21 U.S.C. section 352(r), which it claims "reveals a clear intent to control the content of

'all advertisements' of a restricted device". (J.S. at 10). However, this position is thoroughly negated by both the language of the statute itself and the F.D.A.'s interpretations of its meaning. Section 352(r) reads in relevant part:

> "A drug or device shall be deemed to be misbranded . . .
> **(r) In the case of any restricted device distributed or offered for sale in any state, unless the manufacturer, packer or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type of at least half as large as that used for any trade or grant name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications. . .**"

The statute, in requiring that any advertisements contain a "brief statement of the intended use of the device", does not mandate or encourage hearing aid advertising, as appellant claims. It only requires that *if* medical devices are advertised, they must contain the required warnings.

Moreover, it certainly does not require "performance claim" or "product promotion" advertising like the appellant's; it only requires an objective statement of the uses of the device (*i.e.,* "hearing aids are used to amplify sound").

The F.D.A. has interpreted section 352(r) as leaving the field of hearing aid sales practices, including advertising, to the Federal Trade Commission. Prior to the F.D.A.'s

regulations, the F.T.C. had proposed to regulate hearing aid sales practices. Its regulations would require warnings and prohibit certain representations in hearing aid advertising. 40 Fed.Reg. 26646 (June 24, 1975); the F.T.C. regulations expressly would *not* preempt state laws which provide consumers greater rights. 40 Fed.Reg. 26651.

These F.T.C. advertising regulations "complement rather than conflict" with the F.D.A.'s labeling regulations, in the view of the F.D.A. 42 Fed.Reg. at 9286. Noting that the F.T.C.'s regulations are "particularly within the F.T.C. statutory mandate and expertise", the F.D.A. expressly stated its intent to leave federal regulation of the field of hearing aid advertising to the F.T.C. *Ibid.*[17]

The F.D.A.'s opinion on this matter is entitled to great weight, especially since it involves the construction of a new statute by the agency Congress has chosen to implement it. *Udall v. Tallman,* 380 U.S. 1, 16 (1965); *see,* cases cited in *New Jersey Guild of Hearing Aid Dispensers v. Long, supra,* 384 A.2d at 810.

2. Appellant Can Comply With Both Section 26463(m) And Federal Law, And Thus Section 26463(m) Is Not "Different From, Or In Addition To" Any Federal Requirement Pertaining To Hearing Aids.

Even assuming that there are federal "requirements" relating to hearing aid advertisements, they clearly are not "different from, or in addition to" California's Sherman

[17]Indeed, this policy is expressed in the F.D.A.'s July 26 proposed ruling that section 26463(m) is not preempted by federal law; the F.D.A. said "if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521 (a) of the act." 43 Fed.Reg. at 33182.

Act prohibition. Under *Jones v. Roth Packing Co., supra,* a state law is not "different from" a federal requirement if it is possible to comply with the state requirement without violating any federal requirements. This Court said in *Jones:*

> "Since it would be possible to comply with the state law without triggering federal enforcement action we conclude that the state requirement is not inconsistent with federal law." (430 U.S. at 540).[18]

In the instant case, the information which must be included under 21 U.S.C. section 352(r) if hearing aids are advertised is not inconsistent with section 26463(m). A statement of the "intended uses of the device and relevant warnings, precautions, side effects, and contra-indications" does not require appellant to represent that hearing aids will have an effect on "diseases or disorders of the ear"; it can be easily complied with by simply saying that hearing aids "amplify sound".

Moreover, the main thrust of the F.D.A. regulations is to encourage persons with hearing disorders to have a *medical* evaluation, not to buy a hearing aid like they would buy a freezer or a vacuum cleaner. In explaining its medical evaluation requirement, the F.D.A. said:

> "[T]he medical evaluation requirement is based principally on the recognition that an unnecessary or partially effective hearing aid may be substituted for primary medical or surgical treatment, thus depriving the hearing impaired patient of the benefit of appropriate medical diagnosis and care and resulting in a detriment to health. In addition to delaying proper medical

[18]*See also, New Jersey Guild of Hearing Aid Dispensers v. Long, supra.*

> diagnosis and possibly reducing the efficacy of corrective treatment, the purchase of a hearing aid which cannot attain its intended effect undoubtedly involves a high and unnecessary cost to the consumer. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased." (41 Fed.Reg. 16760).

This policy is entirely complementary to, not "different from", that expressed in section 26463(m). It is totally *inconsistent* with the tone and purpose of appellant's advertising campaign.

Indeed, the F.D.A. has recognized the problems caused by hearing aid advertisements in the past. Thus, it requires a specific disclaimer as to the effects of hearing aids in its labeling requirements. The User Informational Brochure packaged with each aid must contain "a statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions." 21 C.F.R. §801.420 (c) (1) (viii). The F.D.A.'s rationale for this labeling requirement is totally consistent with the California statute's purposes with respect to advertising:

> "The Commissioner believes that the statement in the proposal that hearing aids do not restore normal hearing and do not prevent or improve hearing loss is necessary to protect prospective hearing aid users from misleading claims about the benefits to be expected from a hearing aid and, accordingly, is retaining the requirement that this statement appear in the User Instructional Brochure. Some promotional material for hearing aids, in the past, has been worded to imply that the hearing aid would restore normal hearing or would prevent or improve the organic conditions causing hearing loss." (42 Fed.Reg. at 9291).

3. Even If Section 26463(m) Meets The Standards Set Out In Section 521(a) Of The Act, It Is Exempt From Preemption Under Section 521(b) Because It Is More Stringent Than Federal Law.

Even assuming *arguendo* that section 26463 meets the prerequisites of section 521(a) of the Act, it is clearly more stringent than the federal requirements and thus exempt from preemption under section 521(b). Indeed, as we have noted (*ante*, pp. 16-17), the F.D.A. has already proposed to exempt section 26463(m) from preemption, on the grounds that "to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the F.D.A. requirements". 43 Fed.Reg. at 33182.

4. Given The Statutory Mechanism Congress Has Created For Determining Preemption, The Implicit Preemption Doctrine Is Inapplicable To The Instant Case.

Appellant argues that even if the federal law does not explicitly preempt the entire field of hearing aid advertising, section 26463(m) is still contrary to federal law and thus invalid under the Supremacy Clause. However, in light of the detailed standards and procedures established by Congress to determine preemption, there is no place for the application of the implicit preemption doctrine in this case.

In the field of medical device regulation, Congress has provided that state regulatory law is not to be considered as an obstacle to the purposes of federal law *unless* it is determined to be so by the Food and Drug Administration.

In these circumstances, appellees submit that it would be inappropriate to evaluate, independent of the preemption procedure established by Congress, whether the state statute conflicts with the federal Act. By establishing such a preemption process, Congress anticipated that federal regulation would not be exclusive, and a determination by the courts based on their reading of the Act might well conflict with the degree of federal preemption that Congress envisioned—*i.e.*, what the F.D.A. determines should be regulated by the states under sections 521(a) and (b). *See, New Jersey Guild of Hearing Aid Dispensers v. Long, supra,* 384 A.2d at 813.

None of the cases cited by appellant (J.S. at 16) involve a similar delegation of the responsibility for determining preemption to the federal agency enforcing federal law. Thus, *Jones v. Rath, supra,* and other similar cases appellant relies on are wholly inapposite here, where Congress has entrusted responsibility for determining preemption to the F.D.A., not to the courts.

Moreover, Congress' creation of a mechanism to exempt more stringent state laws from preemption "is persuasive evidence of a Congressional intent to permit supplementary state regulation in the same field". *New Jersey Guild of Hearing Aid Dispensers v. Long, supra,* 384 A.2d at 813. Thus, as the New Jersey Supreme Court cogently stated:

> "[I]n view of the establishment of this innovative exemption mechanism, it seems accurate to say that there is nothing 'implicitly contained in [the FDCA's] structure and purpose,' *Jones, supra,* 430 U.S. at 525 . . . from which an unambiguous Congressional intent to preempt concurrent state regulation is reasonably inferable." (*Id.* at 814).

Therefore, as the New Jersey Supreme Court found,[19] the implicit preemption doctrine is inapplicable to the Medical Device Amendments of 1976, and to the case *sub judice.*

5. Health and Safety Code Section 26463(m) Does Not Conflict With Federal Policy, But Rather Complements It By Buttressing The Medical Evaluation Requirement And Requiring Medical Devices To Be Safe For Self-Medication Before They Are Advertised To The Public.

Appellant's conflict argument also must fail because California's section 26463(m) is entirely consistent with the policies expressed by Congress and the F.D.A. Under the implicit preemption doctrine, preemption only results where compliance with both federal and state regulations is "a physical impossibility"[20] or where the state law "stands as an obstacle to the full purposes and objectives of Congress."[21] As we have shown, however, nothing in the California statutory scheme requires hearing aid manufacturers to violate federal law.

Moreover, the state and federal provisions fully complement each other, to the public's benefit. California's law is designed to discourage self-help treatment of hear-

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[19] 384 A.2d at 814.

[20] *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143 (1963).

[21] *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941).

ing disorders and diseases, and to encourage medical evaluation. It is also designed to prevent the public from being exploited by medical device manufacturers hawking expensive devices with alluring promises of relief from medical conditions. (*See,* section 26465). These are precisely the same purposes sought to be served by the F.D.A. regulations. (*See* 41 Fed.Reg. at 16760, quoted *ante* at pp. 25-26; 42 Fed.Reg. at 9288.)[22]

Thus, the preemption issue raised by appellant presents no substantial federal question requiring this Court to assume jurisdiction of this case.

II. The Court Below Was Correct In Holding That Health And Safety Code Section 26463(m) And The Injunction Issued Pursuant To It Do Not Infringe Upon Appellant's Constitutional Right To Free Speech.

A. A Ruling On The Constitutional Issue Raised By Appellant Is Inappropriate And Unnecessary.

1. The Constitutional Issue Raised Here Was Not Decided By The Court Below Because The Court Correctly Found That Appellant's Advertisments Were Misleading And Thus Not Constitutionally Protected.

Appellant argues that section 26463(m) is unconstitutional because it prohibits the dissemination of truthful

[22]It is noteworthy that the F.D.A.'s endorsement of "ethical selling practices" by hearing aid dispensers cited by appellant (J.S. at 17) is not an endorsement of hearing aid advertising. Instead, it refers to "trial-rental or purchase option" plans that allow the customer to experiment with different hearing aids *after* having had a medical evaluation.

representations. (J.S. at 21). However, the court of appeal made a specific factual determination that appellant's advertisements were *not* truthful; instead, they were misleading and unlawful because they convey the false impression that hearing aids will have a curative or therapeutic effect on hearing loss. (J.S. at 31-32). As such, the court properly held that Dahlberg's advertisements fall outside the scope of the First Amendment. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976) (hereafter the *"Virginia"* case); *Bates v. State Bar of Arizona,* 433 U.S. 350, 383 (1977) (hereafter the *"Bates"* case).

Appellant virtually admits that the advertisements it ran in magazines of national circulation were misleading; it nowhere contests the finding of the court below. Indeed, it concedes that hearing aids are "not 'curative or therapeutic devices' " (J.S. at 21), although, as the court below correctly found, that is the impression conveyed by the advertisements.[23] As such, the court below correctly declined to rule on the constitutional issue raised here by appellant, and that issue is not properly before this Court. Rule 16(b), Rules of the Supreme Court of the United States.

2. Appellant Cannot Challenge The Statute's Effect On Non-misleading Advertising Because The "Overbreadth" Doctrine Is Not Applicable To Claims Of Infringement On The Right To Free Speech.

Appellant argues that regardless of whether its advertisements are truthful, it should be permitted to challenge

[23]See Exhibit 1.

the statute's applicability to truthful advertisements under the "overbreadth" doctrine. But as Justice Blackmun instructed in *Bates, supra,* the overbreadth doctrine has little relevance in commercial speech cases:

> ". . . the justification for the application of overbreadth analysis applies weakly, if at all, in the ordinary commercial context. As was acknowledged in *Virginia Pharmacy Board v. Virginia Consumer Council*, 425 U.S. at 771 n.24, there are 'commonsense differences' between commercial speech and other varieties. See also *id.*, at 775-781 . . . . Since advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation." (433 U.S. at 380-381).

Appellant, however, asserts that there are "compelling reasons" why this Court should ignore its own prior ruling in this case. (J.S. at 22). The reasons it offers, however, are hardly compelling; in fact, they are simply a rehash of the same arguments it makes on the merits of its constitutional claim,[24] not reasons for applying the overbreadth doctrine to commercial free speech cases.

The truth of the matter is that appellant has never presented a "truthful" advertisement to this Court, to the courts below, or to the California Department of Health. If appellant has real objections to California's regulation of truthful advertising, it is not unreasonable to require it to demonstrate the kinds of truthful advertisements it

[24]For example, appellant argues that the state statute frustrates the purposes of the federal Food and Drug Act. Even if true, the relevance of that point to this Court's overbreadth doctrine is tenuous at best. Moreover, as we have shown (*supra*, pp. 29-30), and as the F.D.A. has indicated, section 26463(m) fully complements the federal Act and regulations.

wishes to circulate. As Justice Blackmun noted in *Bates,* there are "common sense differences" between commercial speech and other types of protected speech.[25] Unlike other types of protected speech, a requirement that appellant demonstrates its own commercial speech is protected imposes no undue burden on it; on the other hand, the grave dangers to public health that have resulted from appellant's prior advertising practices demand no less.

3. The First Amendment Issue Was Not Timely Raised.

Resolution of the constitutional issue raised by appellant also is not appropriate because it is well established that this Court will not pass on the constitutionality of a state statute unless a party has consistently presented its claim throughout the proceedings below. Rule 16(b); *Cohen v. California,* 408 U.S. 15 (1971); *Street v. New York,* 394 U.S. 576 (1969).

Appellant did not contest the constitutionality of section 26463 in the trial court, but first raised it on appeal to the state District Court of Appeal.[26] By failing to assert its constitutional claim in the trial court, appellant is not entitled to review by this Court of that claim.

[25]*Bates, supra,* 433 U.S. at 381.

[26]Appellant contends that it is excused from raising the First Amendment issue in the trial court because this Court's decision in *Virginia State Bd. of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) "had not yet been announced". (J.S. at 7). No authority is cited to support its contention that a subsequent decision excuses its failure to raise the issue in the trial court. Moreover, contrary to appellant's assertion, the "commercial free speech" issue had been raised and decided before three judge courts in both the *Virginia case* (373 F.Supp. 683 (E.D. Va. 1974)) and, in California, in *Terry v. Calif. State Bd. of Pharmacy,* 395

B. Section 26463 Is A Valid Exercise Of The State's Authority To Protect The Public Health, Safety And Welfare, And Therefore Is Constitutional.

1. The Purposes Of Section 26463(m) Are To Protect The Public Health, Safety, And Welfare, And Thus Fall Within The State's Traditional Police Powers.

Assuming *arguendo* that appellant is entitled to raise the issue, it is clear that California Health and Safety Code section 26463 is constitutional.

As the trial court noted, section 26463 was adopted in order to implement two important legislative policies:

(1) To encourage the general public to seek qualified medical care for the conditions listed in section 26463; and

(2) To prevent the commercial exploitation of the general public by clever advertisements of drugs or devices, devices that may be useful in the proper circumstances and manner, but whose use the general public is unable to diagnose for itself. (J.S. at 41).

Given these clear and undisputable public purposes, the constitutionality of Health and Safety Code section 26463 and its predecessor statutes has been repeatedly upheld by the California courts as within the state's

F.Supp. 94 (N.D. Cal. 1975), *sum. aff'd.* 426 U.S. 913 (1976), prior to the time plaintiffs filed their motion for summary judgment in this case. Indeed, this Court noted that *prior* to the hearing in the trial court, "the notion of unprotected 'commercial speech' all but passed from the scene" (*Virginia State Bd. of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc., supra,* 425 U.S. at 759) as a result of this Court's landmark decision in *Bigelow v. Virginia,* 421 U.S. 809 (1975). Thus, appellant's claim that it believed commercial speech to be unprotected cannot excuse its failure to timely raise the issue.

police power. *People v. Ryan,* 101 Cal.App.2d 927, 226 P.2d 376 (1951); *People v. Galway,* 120 Cal.App.2d 45, 260 P.2d 212 (1953); *People v. Hohensee,* 251 Cal.App.2d 193, 59 Cal.Rptr. 234 (1967).

This Court has likewise recognized the important state interests in regulating advertising in the public health area. In *Semler v. Oregon State Bd. of Dental Examiners,* 294 U.S. 608 (1935), this Court upheld a statute restricting advertising by dentists; it stated:

> "The legislature was not dealing with traders in commodities, but with the vital interest of public health, and with a profession treating bodily ills and demanding different standards of conduct from those which are traditional in the competition of the market place. The community is concerned with the maintenance of professional standards which will insure not only competency in individual practitioners, but protection against those who would prey upon a public peculiarly susceptible to imposition through alluring promises of physical relief." (294 U.S. at 612).

This rationale is directly applicable to sellers of medical devices like hearing aids; the protection from "alluring promises of physical relief" afforded by section 26463 is similarly necessary to protect the health of California's residents.

2. Section 26463's Prohibition of Performance Claim Advertisements Is Valid In Light Of The Recent "Commercial Speech" Cases.

Appellant cites this Court's recent decisions in the *Virginia* and *Bates* cases in support of its argument that section 26463 violates its First Amendment free speech

rights. However, both the *Virginia* and *Bates* cases dealt solely with price advertising, not performance claim advertising like the instant case. Although appellant attempts to minimize the importance of the distinction between price advertising and performance claim advertising (J.S. at 25), this Court has recognized that the distinction is critical.

In *Bates*, this Court held that Arizona's prohibition against advertisements of the prices of routine attorney services was unconstitutional. In so doing, however, this Court recognized that performance claim advertising (or advertising going to the quality of or need for goods and services) may properly be subjected to regulation to protect the public interest, without running afoul of the First Amendment:

> "[B]ecause the public lacks the sophistication concerning legal services, misstatements that might be overlooked or deemed unimportant in other advertising may be found quite inappropriate in legal advertising. For example, advertising claims as to the quality of services —a matter we do not address today—are not susceptible to measurement or verification; accordingly, such claims may be so likely to be misleading as to warrant restriction." (433 U.S. at 383-384). (Footnote omitted).

As the trial court below noted, to allow unrestricted advertising of medical devices would pose serious threats to the public health by increasing the likelihood that physical ailments will be misdiagnosed and thus receive improper treatment—or undiagnosed and receive no treatment at all until it is too late. Thus, the dangers created by unrestricted performance claim advertising of medical devices like hearing aids are at least equal to the potential dangers of unregulated attorney advertising at issue in *Bates*.

The distinction between price and product promotion advertising was similarly articulated in *Terry v. California State Board of Pharmacy*, 395 F.Supp. 94 (N.D. Cal. 1975), *sum. aff'd.* 426 U.S. 913 (1976). In that case, a three-judge district court struck down as violative of the First Amendment a California statute prohibiting price advertising of prescription drugs. In so doing, the court stated that its decision was limited to price advertising, and that it would have reached a different result if the statute had dealt with product promotion or performance claim advertising:

> "It is undisputed that promotional product advertising is less vigorously protected than other forms of speech . . . 'Promoting the sale of a product is not ordinarily associated with any of the interests the First Amendment seeks to protect. As a rule, it does not affect the political process, does not contribute to the exchange of ideas, does not provide information on matters of public importance, and is not, except perhaps for the ad-men, a form of individual self-expression. It is rather a form of merchandising subject to limitation for public purposes like other business practices.'" (395 F.Supp. at 101-102, *quoting Banzhaf v. F.C.C.*, 405 F.2d 1082, 1101-1102 (D.C. Cir. 1968) *cert. denied* 396 U.S. 842 (1969)).

The court then contrasted price advertising of prescription drugs with product promotion advertising:

> "Prescription drugs may only be purchased when medically necessary. The consumer does not freely choose to buy the product; he is directed to do so by his physician. The information sought here will make it more likely that plaintiffs will be able to purchase these health essential items. The promotional advertising of cigarettes and submarine tours seeks to generate new

demand for goods by consumers who had expressed no previous interest in the products. By touting the virtues of the product, the advertising is intended to create a commercial transaction that would not otherwise occur. Insofar as the information sought here will create commercial transactions that would not otherwise occur, the health needs of the society are served, since a physician has already determined that the prescription drug, the product purchased, is medically necessary to the well-being of the consumer-patient. Further, the advertising sought here is limited to price and does not extend to promotional gimmicks extolling the product and generating artificial demand." (395 F.Supp. at 102).[27]

In the instant case, "the health needs of the society" are best protected by upholding section 26463—not by striking it down. The danger of allowing "promotional gimmicks" "extolling" hearing aids that create an "artificial demand" for them is very much present. Moreover, since there is no requirement that hearing aids only be purchased with a prescription, this danger is compounded because this "artificial demand" is often at the expense of proper medical treatment. Thus, the restrictions imposed by section 26463 are justified.

[27]The *Terry* rationale is in line with other cases which have held that promotional product advertising is entitled to significantly less protection than other forms of speech. *See, Banzhaf v. F.C.C.*, 405 F.2d 1082 (D.C. Cir. 1968), *cert. den.* 396 U.S. 842 (1969), affirming an FCC requirement that broadcasters who carry cigarette advertising must also provide a significant amount of time for presentation of anti-cigarette messages; *see also, Capital Broadcasting Co. v. Mitchell*, 333 F.Supp. 582 (D. D.C. 1971) (three judge court), *sum. aff'd.* 405 U.S. 1000 (1972), upholding the legislative ban of cigarette advertising in the electronic media.

3. The Significant And Compelling Public Policy Considerations Behind Section 26463 Justify Its Advertising Restrictions.

In balancing the State of California's interests against appellant's, it is clear that whatever First Amendment interests appellant may have at stake here are more than outweighed by the compelling public policy considerations behind section 26463.

In the present case, the appellant's interest in freedom of expression is relatively limited for several reasons. First, the restricted speech involves performance claim advertising of medical devices which, unlike *Virginia* and *Terry*, is not strictly informational; instead, it is subjective, self-serving, and beyond the capacity of the public to evaluate for itself. As such, it is "so likely to be misleading as to warrant restriction". *Bates, supra,* 433 U.S. at 383-384.[28]

Second, the appellant's sole interest as a manufacturer and advertiser is pecuniary.[29]

Third, and most important, given the underlying purposes of section 26463(m), the appellant's interests do not coincide with those of the general public but, in fact, conflict with the public interest. Unlike the *Virginia* case, where this Court found that the suppression of price advertising "hits the hardest [at] the poor, the sick, and particularly the aged" (425 U.S. at 763), in the instant case, it is this same group who is most often victimized by alluring promises of relief from hearing aid advertisers. (C.T. 303).

[28]*See also, Terry, supra,* 395 F.Supp. at 101.

[29]To the extent appellant may be interested in upgrading the level of knowledge about hearing aids, it may make performance claims about them in trade and medical journals despite section 26463(m). California Health & Saf. Code § 26464.

In contrast to the appellant's interests, the State's interests in enforcing section 26463(m) are compelling. Performance-type advertising for most drugs and devices must be regulated both because it may be dangerous, and because so many people are susceptible to manipulative and misleading advertisements inducing them to purchase useless devices.[30]

The findings by the United States Department of Health, Education and Welfare set out in *A Report of Hearing Aid Health Care* (C.T. 125-194, discussed *ante*, at p. 7) noted that approximately 70 percent of the persons who buy hearing aids go to a dealer first rather than to a physician. This can only be the result of the extensive advertising practiced in the hearing aid industry. Indeed, in this case, Dahlberg's advertisements produced almost 12,000 responses from California residents to its ads in a little over one year. (C.T. 213). Each of these persons then received a call or visit from a hearing aid dealer, rather than medical treatment. The tragic result of this unregulated advertising, as the HEW report noted, is that many persons with remedial ear disease go undiagnosed, trying one hearing aid after another, until they reach the point where the disease is no longer medically remediable. (C.T. 142). Moreover, the HEW report noted that in 40 percent of the cases studied in New York City and Baltimore, dealers recommended the purchase of hearing aids for persons when audiological centers had determined that the patient could not be helped by a hearing aid. (C.T. 133).

[30]*See, California Cancer Quack Laws: The Best Is None Too Good*, 40 So. Cal.L.Rev. 384 (1967).

The interests of the State of California and the lay public in preventing these abuses is clearly served by Health and Safety Code section 26463(m), and more than justify the limited restrictions placed on the appellant in this case.

C. The Advertising Prohibitions Of Section 26463 Are Not Overbroad Since They Utilize The Narrowest Approach Possible In Effectuating A Legitimate And Compelling Public Policy.

Appellant argues that section 26463 is unconstitutional because it prohibits truthful as well as false and misleading representations, and is therefore overbroad under the First Amendment. Assuming *arguendo* that it has standing to raise this argument, appellant's argument is without merit for several reasons.

First, as we have shown, a restriction on advertising of non-certified medical drugs and devices, whether true or false, is necessary to carry out the purposes of section 26463 because of the irreparable nature of the dangers to the public the statute seeks to prevent.

Second, Health and Safety Code section 26465 provides clear and precise standards under which proper medical device advertising is allowed. It also provides for an administrative determination by the California Department of Health that truthful performance claim advertising will be allowed if the drug or device is determined to be "safe and effective" self-medication. If appellant's advertisements do not present a danger to the general public, then they will be approved and can be used.[31] Thus, section

[31]*Cf.* Health and Safety Code section 26464.

26463's prohibition on truthful advertising is only as broad as is necessary to carry out its purposes.[32]

Third, contrary to appellant's assertions, the wording of the injunction is not overly broad. The injunction simply tracks the language of section 26463(m). To require the injunction to go only to the advertisements before the court would allow appellant to freely circumvent the statute by using different, but similarly objectionable, advertisements. This Court has recognized that courts must have some latitude in making orders to prohibit such illegal activity:

> "We think it reasonable for the Commission to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future advertisements. As was said in *Federal Trade Commission v. Ruberoid Co.*, 343 U.S. 470, 473, '[T]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past.' Having been caught violating the Act, respondents 'must expect some fencing in'." (*Federal Trade Commission v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965)).

[32]Appellant argues that the protections afforded by section 26465 are inadequate because there is no guarantee that the Department of Health will allow truthful advertising under that section. However, this argument is purely speculative and hypothetical, since the appellant has never tried to obtain permission to advertise its hearing aids. It assumes, without any justification or basis, that the State of California will act in bad faith.

Moreover, California law provides adequate procedural protections for the appellant should the Department of Health act arbitrarily. As appellant notes, under California Government Code section 11427, appellant has the right to petition the Department of Health to promulgate a regulation allowing it to advertise hearing aids in compliance with section 26465. If the Department of Health, despite the mandatory language of section 26465, should refuse to consider Dahlberg's application for approval of its advertisements, Dahlberg can obtain a writ of mandate requiring the Department to act, pursuant to California Code of Civil Procedure section 1085. Should the Department deny the application, Dahlberg can seek judicial review of that decision pursuant either to Code of Civil Procedure sections 1085 or 1094.5. *See, e.g., Carmona v. Division of Industrial Safety*, 13 Cal.3d 303, 309, 118 Cal.Rptr. 473 (1975).

Finally, sections 26463 and 26465 do not constitute an invalid prior restraint of freedom of speech. Appellant wrongly claims that the statutes carry a heavy presumption against their constitutional validity in light of the *Virginia* case; as we have shown (*ante*, pp. 35-38), however, the statutes at issue clearly meet the constitutional standards set forth in the *Virginia* and *Bates* cases.

Furthermore, section 26465 sets out clear and specific standards for when advertisements should be approved. Thus, the danger of unreviewable, standardless prior restraints is not present here.

Lastly, as discussed previously, this Court held in *Bates* that the overbreadth doctrine was not justified in commercial speech cases because there are "'common sense differences' between commercial speech and other varieties," and because it was "not necessary to further its intended objective". (433 U.S. at 381). This reasoning is equally applicable to the issue of prior restraint. No case has yet held the prior restraint doctrine applicable to purely commercial speech, and there is no reason to do so here. The interests of the general public in obtaining proper medical treatment and avoiding inappropriate medical devices far outweighs whatever harm, if any, is caused appellant by the restrictions on its product promotion advertising im-

posed under California law. An application of the prior restraint doctrine in this case would be unwarranted.

Thus, this case presents no substantial question as to the constitutionality of California Health and Safety Code section 26463(m).

CONCLUSION

For the reasons stated herein, the appeal should be dismissed, or the judgment of the court below affirmed.

Respectfully submitted,

RICHARD M. PEARL
California Rural Legal Assistance
JAMES RUMBLE
Attorneys for Appellees
George Kievlan, et al.

(Exhibits Follow)

Exhibits

EXHIBIT 1

GENTLEMEN:

Please tell me how I may be able to hear again more clearly in both ears without using hearing aids that have cords or tubes

JUST BILLS...WHAT'S THIS?

Your Name_____

Address_____

City_____

State_____ Zip Code_____

I Am Now Using (check one)

☐ Cord Type ☐ Behind the Ear Type

☐ Eyeglass Type ☐ No Aid

I understand that mailing this card places me under no obligation.

Tear off and mail today—no postage necessary

MAGAZINES ADVERTISING

I'M NOT DEAF!

Under normal conditions I hear well enough. But sometimes my ultra-miniature DAHLBERG MIRACLE-EAR® hearing aid is a blessing. I just put it in my ear and I hear more clearly.

It is so natural sounding — nothing above my ear or below my ear. Nothing behind or in front of my ear. No tubes, nor wires. No scratchy sounds.

It is especially designed for those who hear but do not always understand — a classic symptom of nerve impairment. If diagnosis* shows you have this type of loss, this modern hearing aid may give you the extra "lift" you need to live a full and active life.

Rush this coupon! Discover how you may be able to hear again in both ears without using hearing aids that have cords or tubes. NO OBLIGATION WHATEVER. * *Ask your doctor about Dahlberg Hearing Aids.*

MIRACLE-EAR®
P.O. Box 549, Dept. OG-373
Minneapolis, Minn. 55440

Please tell me how I may be able to hear again in both ears without using hearing aids that have cords or tubes.

NAME_____

ADDRESS_____

CITY_____ STATE_____ ZIP_____

IF YOUR DOCTOR SAYS YOU HAVE NERVE DEAFNESS . . .

THIS IS ALL YOU WEAR!

Miracle-Ear® may be all you need to hear clearly again. It fits entirely in your ear. Ideal for 7 out of 10 who can still hear but have trouble understanding words. Try it today. Come in, phone, or send the coupon.

Available only at our offices.

SHOWN TWICE THE ACTUAL SIZE.

Name _____

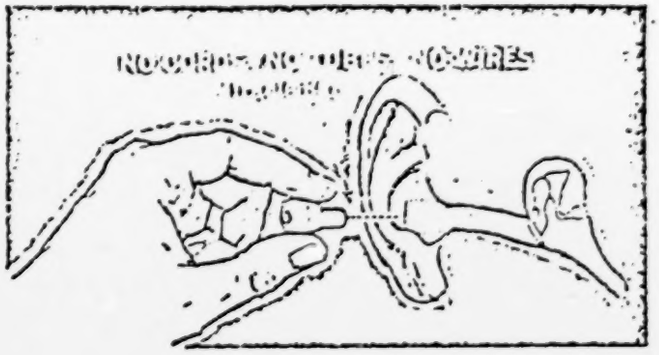
Address _____

City _____

State _____ Zip____

PROFESSIONAL HEARING AID CENTER
531 Hartnell 372-4293 Monterey

MILD NERVE DEAFNESS
The most common cause of hearing loss



Don't let another day go by before YOU realize how thrilling it could be to HEAR AGAIN more clearly! MIRACLE-EAR developed and patented by Dahlberg, may be EXACTLY what YOU have been hoping for!

PROFESSIONAL HEARING AID CENTER
531 Hartnell 372-4293 Monterey

Exhibit 2

United States District Court
Eastern District of New York

Docket No. 76 C 1565

New York State Hearing Aid Society Incorporated, et al.,
Plaintiffs,
— against —
State of New York, et al.,
Defendants.

MEMORANDUM AND ORDER

PRATT, J.:

Plaintiffs, individual hearing aid dealers and membership corporations composed of individual hearing aid dealers, have brought this action to declare unconstitutional and to enjoin enforcement of Chapter 274 of the Laws of 1976 of the State of New York, New York General Business Law §§ 780 *et seq.*, which established a regulatory scheme for the sale of hearing aids in New York State. The complaint is premised upon the supremacy clause in Article VI, § 2, of the Constitution, which, when coupled with the specific prohibition of 21 USC § 360k, plaintiffs urge, precludes the state from continuing or enforcing any regulation which conflicts with the national regulatory scheme for

the manufacture and sale of hearing aids embodied in 21 USC §§ 360 *et seq.*

In a memorandum and order dated December 3, 1976, the undersigned denied as premature a motion made by these plaintiffs to preliminarily enjoin enforcement of Chapter 274. By motion returnable March 10, 1977, plaintiffs both renewed their request for a preliminary injunction and sought summary judgment on their claims for declaratory and injunctive relief. Since the federal regulations were not yet in full force and effect, however, those applications were again denied as premature in a memorandum and order dated March 17, 1977. On August 25, 1977 the federal regulations took effect, and now before the court are plaintiffs' renewed motions for preliminary injunction and summary judgment, as well as defendants' crossmotion to dismiss pursuant to FRCP 12(b)(6).

I.

Preliminarily, defendants have challenged, and the court has examined, the standing of these plaintiffs to litigate the constitutionality of Chapter 274. Not only have the individual plaintiffs averred "actionable causal relationship" between the challenged regulations and their injury, *Warth v. Seldin,* 422 US 490, 507 (1975); *Village of Arlington Heights v. Metropolitan Housing Development Corp.,* 429 US 252 (1977), but the membership corporations also have averred the requisite factors enumerated in *Warth, supra* and *Hunt v. Washington State Apple Advertising Commission,* 97 SCt 2434 (1977). Moreover, defendants' assertions to the contrary notwithstanding, the issue is "ripe" for adjudication as will be more fully explained *infra.*

Section 360k of Title 21 of the United States Code provides, in part, that:

> [N]o State * * * may establish or continue in effect with respect to a device [such as a hearing aid] intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Defendants concede that part of the state regulatory scheme has been superseded by the federal regulations. In an affidavit filed September 16, 1977, plaintiffs' attorney wrote:

> 3. That on or about August 31, 1977 the Department of State of the State of New York, by Mario Cuomo, Secretary of State, issued a statement concerning the hearing aid statutes and the federal regulations. A copy of said statement is annexed hereto and marked as Exhibit A.
>
> 4. That your deponent respectfully submits that by said statement the defendant, the Secretary of State of the State of New York, has conceded that the federal regulations supersede the state statute in at least the manner set forth in the attached statement.

Not only does this statement fairly characterize the Secretary of State's letter of August 31, 1977, but, in an affidavit filed September 26, 1977, defendants' attorney stated: "I hereby stipulate to and acknowledge the accuracy of paragraph '3' and '4' of plaintiff's affidavit [filed September 16, 1977]." However, defendants contend that not

all of the state's requirements have been superseded, and that the remaining ones must be complied with. In his letter dated August 31, 1977 the Secretary of State went on to declare:

> The State requirement that a hearing aid dealer must be registered with this department in order to fit and sell hearing aids continues in effect. Other aspects of the State law and the rules of this department including but not limited to the provisions as to the 30-day guarantee, the receipt that must be provided, the required availability of repair and service, prohibitions against canvassing, et al. continue and must be complied with in all events.
>
> You are further advised that the federal food, drug and cosmetic act, the law under which the FDS regulations were adopted, permits the state to apply for exemptions for state requirements which are more stringent than those effected by the federal regulations. Requests for such exemptions are being made. Until you are advised otherwise, however, you must follow the federal regulations as indicated above.

Plaintiff's Aff. of September 16, 1977, Ex. A.

In its present form the controversy, simply stated, is that plaintiffs disagree with the Secretary of State when he says that the federal regulations did not supersede Chapter 274's provisions prohibiting door-to-door canvassing, regulating the availability of repairs and service, regulating the receipts and written documents to be given to hearing aid customers, the 30-day guarantee provisions, etc.

III.

Summary judgment shall be granted on their request for declaratory relief, insofar as New York's Secretary of State continues in the erroneous belief that New York **General** Business Law §§ 780 *et seq.* has not been superseded by the federal regulations governing the manufacture and production of a hearing aid device. The intent and effect of 21 USC §§ 360 *et seq.* and the regulations promulgated thereunder reserve to the federal government the power to control the manufacture, production, effectiveness, and standards relating to devices such as hearing aids. The supremacy clause of the Constitution and the clear prohibition of 21 USC § 360k, then, preclude the continuance and enforcement of those sections of New York General Business Law §§ 780 *et seq.* which also purport to regulate hearing aid devices.

Defendants correctly note that the State of New York may apply pursuant to 21 USC § 360k(b) and the regulations promulgated thereunder for an exemption from the federal regulations. Until such time that an exemption, if warranted, is granted, however, plaintiffs should not be threatened with enforcement of a state statute which, in respect to hearing aid devices themselves, is erroneously thought to be not superseded by the federal regulations.

Specifically, the court declares that the following provisions of the New York General Business Law have been superseded by the federal statutes and regulations:

> § 784(1), conceded by the Secretary of State to have been superseded, and relating to the written recommendations, testing, typing, waivers, etc. required before a hearing aid may be dispensed;

§ 784(3), relating to an itemized receipt;

§784(4), relating to the money-back guarantee and rebate provisions;

§784(9), relating to the disclaimer which must accompany a hearing aid device.

IV.

Insofar as New York General Business Law §§ 780 *et seq.* purports to regulate the vendors of a device rather than the device itself, such as the licensing of dealers, the state statute remains unaffected by 21 USC §§ 360 *et seq.* and the related regulations. The federal regulations are aimed at the safety and effectiveness of devices, not the manner in which they are sold. Thus, while the state statute may not, absent exemptions, regulate guarantees and receipts in the face of superseding federal regulations, neither the supremacy clause of the Constitution nor § 360k of Title 21 prohibits the state from controlling who sells a hearing aid device or the manner in which it is sold.

Specifically, the court declares that the following provisions of the New York General Business Law have not been superseded by the federal statutes and regulations:

§§ 780, 781, 782, and 783, which relate to the legislative intent, definitions, and registration requirements of Chapter 274;

§ 784(2) relating to door-to-door canvassing;

§§ 784(5)-(8), all of which relate to prohibitions against false, misleading, deceptive, or untruthful advertising;

§ 784(10) relating to sanctions;

§ 785 relating to the due process procedures provided should a certificate of registration be denied, suspended, or revoked;

§785-a relating to referrals and not for profit sales;

§ 786 relating to the powers of the Secretary of State to promulgate rules and regulations to effectuate the purposes of this article, of course, as modified by this decision; and

§ 787 relating to the separability of provisions.

Significantly, New York General Business Law § 787 specifically authorizes the selective declarations of invalidity on the specific provisions of Chapter 274 without impairing or invalidating any other sections or provisions of the chapter.

V.

The court is mindful that plaintiffs' complaint seeks a permanent injunction; indeed, plaintiffs have moved for a preliminary injunction. The court is persuaded, however, by defendants' affidavits and statements to the effect that the State of New York has no desire to continue enforcement of a state statute which has been superseded by federal regulations. In the face of an actual controversy between plaintiffs and defendants, a declaratory judgment is appropriate. The state has already suspended enforcement of New York General Business Law §§ 780 *et seq.* insofar as it conflicts with the federal regulations. Even without the state's voluntary compliance, plaintiffs have a complete defense to continued enforcement of the conflict-

ing provisions and, consequently, the court sees no value in entering an "unnecessary" injunction here; the declaratory judgment directed above will dispose of the action in its entirety.

Plaintiffs shall within 10 days submit on notice a proposed judgment for the court's signature.

SO ORDERED.

Dated: Westbury, New York

March 10, 1978.

GEORGE C. PRATT
George C. Pratt
U.S. District Judge

Supreme Court, U. S.
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IN THE

Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

vs.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants

On Appeal from the Court of Appeal of the State of California First Appellate District

APPELLANTS' BRIEF IN OPPOSITION TO MOTION TO DISMISS OR AFFIRM

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REPLY TO APPELLEES' STATEMENT OF THE CASE

In their "Statement of the Case" appellees attempt to characterize appellant's advertising as part of a campaign to defraud the hard of hearing by selling them expensive and unnecessary hearing aids. They claim to have "pre-

sented facts demonstrating the harm caused by [Dahlberg's] advertisements," including "serious and repeated incidents of abusive sales practices used by the local Dahlberg dealer, resulting in the plaintiffs being sold expensive hearing aids which could not or did not help them, and which in several cases were not medically appropriate." (Motion, pp. 6-7). In sole support of this statement, they refer the Court to certain declarations under penalty of perjury, including their own, which are included in the record. (C.T. 32-91). An examination of these declarations will show that appellees' claims are without factual support and are an attempt to mislead the Court.

Appellees' declarations alleged fraudulent practices by one John Maier, a hearing aid dispenser in Santa Cruz County. Mr. Maier's practices, whatever they may have been, had nothing to do with appellant or its advertising. The parties stipulated in the superior court that " . . . no agency relationship existed between the defendants John Maier, LeRoy Stacy, the Professional Hearing Aid Center aka Monterey Peninsula Hearing Aid Center and the defendants Dahlberg Electronics, Inc. or Detection Sciences, Inc." (See Stipulation and Order, C.T. 119-120). Therefore it is misleading to refer to Mr. Maier as the "local Dahlberg dealer."

No declaration was submitted from any of the appellees or from any other person stating that he or she had read a Dahlberg advertisement and had been led thereby to purchase an unnecessary hearing aid or to forego necessary diagnosis and treatment.

1. The Declaration of George Kievlan makes no mention at all of any advertising. (C.T. 32-35).

2. The Declaration of Eris Gofinch states that she saw a piece of advertising, but does not identify it as Dahlberg advertising. (C.T. 45-49).

3. The Declaration of Charles Harrold states that he received a piece of Dahlberg advertising in the mail and responded to it by sending in a post card. But he makes no complaint about the advertising as such, only about the practices of Mr. Maier. (C.T. 53-60).

4. The Declaration of Mary Walker makes no mention at all of Dahlberg advertising. (C.T. 61-65).

5. The Declaration of Gladys Faustine states that she saw and responded to a Dahlberg ad, but does not specifically identify or describe it and makes no complaint about it. (C.T. 66-68).

6. Finally, the Declaration of Minnie Carp states that she saw and responded to a piece of advertising, but does not indicate whether it was Dahlberg advertising. (C.T. 69-70).

To recapitulate, only two of the six appellees state that they saw and responded to Dahlberg advertising, and only one of the two indicates the content of such advertising. No appellee has complained about the nature or content of the advertising as such. Appellees' cause of action for fraud was directed strictly to the practices of an independent hearing aid dispenser, who was not the agent of Dahlberg.

Appellees also refer to a Department of Health, Education and Welfare report which is included in the record and which supposedly found that "misleading advertising and high pressure sales were prevalent in the hearing aid industry." (Motion, p. 7). Without regard to the hearsay nature of the report, which is purely a matter of California evidence law, we simply note that the report makes no reference to Dahlberg or its advertising.

Considering the utter and complete absence of any facts showing that Dahlberg's advertising had any harmful effect on anyone, appellees' argument that Dahlberg failed to produce evidence to the contrary, "although it was its duty to do so under California law" is totally without merit.[1]

ARGUMENT

I

THE DOCTRINE OF PRIMARY ADMINISTRATIVE JURISDICTION DOES NOT APPLY.

Appellees' argument that the F.D.A. has primary administrative jurisdiction over the pre-emption issue is without merit. The doctrine of primary administrative jurisdiction applies to two categories of cases: "[1] cases raising issues of fact not within the conventional experience of judges or

[1]An opponent's failure to file counter-affidavits on a motion for summary judgment admits the truth of the movant's affidavit, but does not relieve the movant from the burden of establishing evidentiary facts of every element necessary to entitle him to judgment. *Brewer v. Reliable Automotive Co.* (1966) 49 Cal.Rptr. 498, 240 C.A.2d 173; *American Soc. of Composers, Authors and Publishers v. Superior Court of Los Angeles County* (1962) 24 Cal. Rptr. 772, 207 C.A.2d 676; *House v. Lala* (1960) 4 Cal.Rptr. 366, 180 C.A.2d 412.

[2] cases requiring the exercise of administrative discretion." *Far East Conference v. U.S.* (1952) 342 U.S. 570, 574, 96 L.Ed. 576, 72 S.Ct. 492.

The pre-emption issue herein is clearly not an issue of fact outside the conventional experience of judges, and therefore the case does not fall within the first category. To the contrary the issue is one of law and wholly within the competence of the judiciary. See *Great N.R. Co. v. Merchants Elevator Co.* (1922) 259 U.S. 285, 66 L.Ed. 943, 42 S.Ct. 477; *Louisville & N.R. Co. v. F. W. Cook Brewing Co.* (1912) 223 U.S. 70, 56 L.Ed. 355, 42 S.Ct. 189.

As to the second category, it is necessary to have in mind that the pre-emption question herein involves two separate and distinct sub-issues: (a) whether the state law has been pre-empted; and (b) if it has been pre-empted, whether it should be exempted from pre-emption. As the following discussion will demonstrate, the first issue is a pure question of statutory construction which can be resolved by this Court, and no prior administrative determination is either necessary or appropriate. Only the second issue has been committed to the exercise of administrative discretion.

A. The question whether the statute has been pre-empted is for the Court and not for the F.D.A.

The doctrine of primary administrative jurisdiction requires a party first to resort to an administrative agency before he may sue for an adjudication involving a question within the competence of that agency. *Armour & Co. v. Alton R. Co.* (1941) 312 U.S. 195, 85 L.Ed. 771, 61 S.Ct. 498. The doctrine determines whether the court or the administrative agency should make the initial decision. *Texas &*

P.R. Co. v. Abilene Cotton Oil Co. (1907) 204 U.S. 426, 51 L.Ed. 553, 27 S.Ct. 350; 3, K. Davis, *Administrative Law Treatise*, sec. 19.01.

The Court should not apply the doctrine to the pre-emption question herein, for to do so the Court would have to extend it beyond all bounds revealed in prior decisions. First, Dahlberg did not initiate this litigation and therefore should not be required to "resort to" an administrative agency. Secondly, the "initial decision" has already been made. The Court of Appeal, acting in accordance with the views expressed by appellees, has rendered a decision that the state statute was not pre-empted. Dahlberg now seeks review of that decision. The case is therefore in an entirely different posture than one where no court decision has been rendered. (Cf. *Annotation, Primary Administrative Jurisdiction*, 38 L.Ed.2d 796, and cases collected therein.)

Appellees did not urge in the Court of Appeal that the question of whether the statute had been pre-empted should be left up to the F.D.A. It now argues this point for the first time in this Court. Dahlberg should not be denied review in this Court at the instance of parties who urged the decision below.

Thirdly, the question of whether the statute has been pre-empted is not actually pending before the F.D.A. No petition or application of any kind seeking to have the F.D.A. make such determination has ever been filed by any party. The only applications before the F.D.A. are from states such as California, seeking to have their statutes exempted from pre-emption.

Finally, and of utmost importance, the question whether the statute has been pre-empted is not within the jurisdiction of the F.D.A. The only question actually within its jurisdiction is whether the statute, having been pre-empted, should now be exempted from pre-emption upon application of the State of California. This distinction has been expressly recognized by the two other state courts which have had occasion to consider this problem. See *New Jersey Guild of Hearing Aid Dispensers, et al. v. Long* (1977) 75 N.J. 544, 384 A.2d 795, 809; *New York State Hearing Aid Society v. State of New York* (E.D.N.Y., March 10, 1978). The latter opinion specifically states that the statute may not be enforced unless and until an exemption is granted. (Motion, Ex. 2, p. 5).

B. A stay of the appeal is not required.

The question of whether the statute should be exempt from pre-emption is admittedly within the jurisdiction of the F.D.A. (21 U.S.C. § 360k(b)). Because the California application for exemption is currently pending before the F.D.A., the Court might be inclined to stay its hand until the F.D.A. has ruled upon the application. *Federal Power Com. v. Louisiana Power and Light Co.* (1972) 406 U.S. 621, 32 L.Ed.2d 369, 92 S.Ct. 1827. Here, however, there are several other considerations which impel the conclusion that the Court should not postpone its consideration of this appeal. Initially, the Court should consider the fact that neither of the parties to this appeal has initiated the proceeding before the F.D.A. The proceeding was initiated by an application of the State of California Department of Health, which was filed over two years ago. The application covers the entire Sherman Food, Drug and Cos-

metic Law and not just the portion of the subject statute which relates to hearing aids.

Of primary importance is the fact that the statute, even if exempt from pre-emption, would still be unconstitutional. The case is therefore akin to *Public Utilities Com. v. United States* (1958) 355 U.S. 534, 2 L.Ed.2d 470, 78 S.Ct. 446, in which the United States brought suit challenging the constitutionality of a California statute prohibiting carriers from transporting government property at rates other than those approved by the California Public Utilities Commission. The Court held that the doctrine of primary administrative jurisdiction did not apply because the constitutional issue was one which the Public Utilities Commission could not be expected to entertain. In so holding the Court stated:

> "But where the only question is whether it is constitutional to fasten the administrative procedure onto the litigant, the administrative agency may be defied and judicial relief sought as the only effective way of protecting the asserted constitutional right. In that posture the case is kin to those that hold that 'failure to apply for a license under an ordinance which on its face violates the Constitution does not preclude review in this Court of a judgment of conviction under such an ordinance.' *Staub v. Baxley*, 355 U.S. 313, 319, 2 L.Ed.2d 302, 309, 78 S.Ct. 277, and cases cited; *Thomas v. Collins*, 323 U.S. 516, 89 L.Ed. 430, 65 S.Ct. 315." (355 U.S. at 540).

Also, as stated in the separate opinion by Justice White (joined by Chief Justice Warren and Justice Brennan), in *Amalgamated Meat Cutters & Butcher Workmen v. Jewel Tea Co.* (1965) 381 U.S. 676, 14 L.Ed.2d 640, 85 S.Ct. 1596,

the doctrine of primary jurisdiction is not a doctrine of futility; it does not require resort to an expensive and merely delaying administrative proceeding when the case must eventually be decided on a controlling legal issue wholly unrelated to determinations for the ascertainment of which the proceeding is to be submitted to the agency.

Appellant submits that in the instant case, no purpose would be served by awaiting the decision of the F.D.A. as to whether the statute should be exempt. Even if the statute were held exempt, it would still be unconstitutional. Furthermore, appellant is being denied its constitutional right to advertise while awaiting the outcome of a very lengthy F.D.A. proceeding. The Court should therefore proceed with the hearing of this appeal without further delay. See *Ricci v. Chicago Mercantile Exchange* (1973) 409 U.S. 289, 34 L.Ed.2d 525, 93 S.Ct. 573 (Marshall, J. dissenting).

C. The appeal should not be dismissed on the basis of the primary administrative jurisdiction doctrine.

Even if the primary administrative jurisdiction doctrine were applicable, dismissal of the appeal would not be appropriate. Application of the doctrine generally results in a stay of the action rather than a dismissal, *United States v. Western R.R. Co.* (1956) 352 U.S. 59, 1 L.Ed.2d 126, 77 S.Ct. 161; *Amalgamated Meat Cutters & Butcher Workmen v. Jewel Tea Co.* (1965) 381 U.S. 676, 14 L.Ed.2d 640, 85 S.Ct. 1596; *International Brotherhood of Boilermakers, etc. v. Hardeman* (1971) 401 U.S. 233, 28 L.Ed.2d 10, 91 S.Ct. 609, reh. den. 402 U.S. 967, 29 L.Ed.2d 132, 91 S.Ct. 1607, particularly where there are rights which may

be saved by retaining the cause. *Mitchell Coal & Coke Co. v. Pennsylvania R. Co.* (1913) 230 U.S. 247, 57 L.Ed. 1472, 33 S.Ct. 916; *General American Tank Car Corp. v. El Dorado Terminal Co.* (1940) 308 U.S. 422, 84 L.Ed. 361, 60 S.Ct. 325, reh. den. 309 U.S. 694, 84 L.Ed. 1035, 60 S.Ct. 465. In *United States v. Michigan National Corp.* (1974) 419 U.S. 1, 42 L.Ed.2d 1, 5, 95 S.Ct. 10, the Court held that a stay of the action, rather than dismissal, would be proper because it could not be said "with assurance" that the Government would not be prejudiced by a dismissal. (419 U.S. at 5).

In the instant case, it would be prejudicial to appellant to dismiss the appeal because its right to present its First Amendment claim would thereby be lost. Appellees argue that if the F.D.A. should deny the state's application for exemption from pre-emption, appellant could successfully move to have the injunction vacated on the basis of change in law. *Sontag Chain Stores Co. v. Superior Court* (1941) 18 Cal.2d 92, 94-95, 113 P.2d 689. While it is true that appellant would have this remedy, there is also the possibility that the F.D.A. may grant the exemption, so that pre-emption would no longer be an issue. If in the meantime the appeal were to be dismissed, appellant would no longer have the opportunity to present the First Amendment issue to this Court.

II

THE STATUTE HAS BEEN PRE-EMPTED.

Appellant's Jurisdictional Statement sets forth the manner in which pre-emption occurred. Appellees nevertheless contend that pre-emption has not occurred and advance

several arguments in support of their contention. None of these arguments has any validity whatever.

A. Specific counterpart regulations have been adopted by the F.D.A.

Appellees first assert that the California law "would be pre-empted only when the F.D.A. had established 'specific counterpart regulations' applicable to the device." (Motion, p. 16). This is erroneous. The regulations, which speak in the disjunctive, state that:

> "State or local requirements are pre-empted only when the Food and Drug Administration has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.*" (21 *C.F.R.* § 808.1(d), emphasis added).

The meaning of "specific counterpart regulations," which is not a statutory term and not defined by the F.D.A., is not entirely clear. There is no specific federal regulation similar to Section 26463, but the federal regulations clearly reach the subject of hearing aid advertising and may well be deemed "counterpart" to Section 26463.

Notwithstanding this ambiguity, however, it is quite clear that there are in fact "other specific requirements applicable to [hearing aids] under the Act," and that the state requirement is divergent therefrom. In particular there is the requirement contained in 21 U.S.C. § 352(r) as to information which *must* be included "in all advertisements and other descriptive printed matter issued or

caused to be issued by the manufacturer, packer or distributor with respect to [the] device." The state law is clearly "different from" this federal requirement because it is impossible to comply with both. *Jones v. Rath Packing Co.* (1977) 430 U.S. 519, 51 L.Ed.2d 604, 97 S.Ct. 1305. See also *New Jersey Guild of Hearing Aid Dispensers, et al. v. Long, supra*, 75 N.J. 544, 384 A.2d 795, 812, in which the pre-sale testing requirement in the New Jersey law was held to have been pre-empted by the federal law because it would operate to create a prerequisite to the sale of a hearing aid that is "in addition to" that specified in the federal regulation even though not "different from" it.

B. The federal law and regulations are directly concerned with advertising.

Appellees also contend that the federal requirements are primarily concerned with labeling, rather than advertising, and that "the F.D.A. regulations totally ignore the field of hearing aid advertising." (Motion, p. 20). This is simply not so.

First, there is no true distinction between "labeling" and "advertising" in the context of this case. As heretofore noted, the term "advertisement" is broadly defined in the California Health and Safety Code as follows:

> "'Advertisement' means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase or use of any food, drug, device or cosmetic." (California Health and Safety Code Section 26002).

This definition would obviously cover a label used on the device or on the container for a device.

Secondly, the federal statute, 21 U.S.C. § 352(r), is not just concerned with "labeling." It is concerned with "all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to [the] device."

Finally, the F.D.A. regulations do speak of labeling, but not in the narrow sense suggested by appellees. As the Commissioner states:

> "The Food and Drug Administration (FDA) is establishing uniform professional and patient labeling requirements and conditions for sale of hearing aid devices. The regulations prescribe the types of information that must be included in the labeling to provide hearing professionals and patients with adequate directions for the safe and effective use of a hearing aid; . . . ." (42 Fed. Reg. 9286).

Directions for the safe and *effective* use of a hearing aid necessarily involve statements which are likely to induce its purchase, either directly or indirectly. Thus the regulations clearly reach "advertisements" within the meaning of California Health and Safety Code section 26002. Whether such directions also constitute "labeling" is simply not relevant to this appeal.

C. It is impossible to comply with both the state law and the federal law and regulations.

Appellees suggest that a hearing aid manufacturer can comply with both federal and state law by limiting its advertising to the simple statement that "hearing aids are used to amplify sound." (Motion, pp. 23, 25). This sug-

gestion only serves to demonstrate the futility of appellees' position and the absurdity of the state law as construed by the court below. A simplistic statement of this kind is not informative to the potential hearing aid user. In no sense can it be said to comply with 21 U.S.C. § 352(r) which requires advertising to contain "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications. . . ." In order to comply with the federal law, a manufacturer who intends to advertise must at least be free to tell the potential user: "If you are hard of hearing, then a hearing aid may help you to hear more clearly," or "If you have trouble hearing, then a hearing aid may compensate for your hearing loss." But such statements are precisely what the state law now forbids.

Appellees suggest that the manufacturer has a simple solution to his dilemma: don't advertise at all. This suggestion is totally unreasonable, contrary to the purpose of the federal law, contrary to the stated position of the F.D.A., and, most importantly, it flies in the face of the First Amendment. A manufacturer simply cannot be put to the choice of either violating federal law or remaining silent.

D. The California statute relates to the effectiveness of hearing aids as well as to the advertising thereof.

Appellees take the erroneous position that a state law will not be pre-empted unless it relates "to the safety or effectiveness of the device." (See 21 U.S.C. § 360k).[2] They argue that the California statute is not concerned with the safety or effectiveness of the device, but rather with sales practices, and therefore it is not pre-empted. There are two difficulties with this view. First, the California Court of Appeal has expressly recognized that the statute *does* relate to the effectiveness of hearing aids. As the Court of Appeal states in discussing the pre-emption issue herein, "[the statute] 'relates to the effectiveness' of hearing aids by prohibiting representations on this subject in copy which advertises them for sale." (J.S., p. 34). See also the portion of the opinion of the Superior Court discussing the purpose of the statute as relating to the "efficacy" of the device. (J.S., p. 41).

The other difficulty with appellees' view is that it involves a misreading of the federal statute. State law requirements which are different from or in addition to federal requirements are pre-empted if they relate "to the safety or ef-

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[2]The F.D.A. also appears to share this mistaken view when it states in its latest pronouncement on the California statute:

> "The Commissioner is also proposing to exempt from pre-emption California's Health and Safety Code, section 26463 (m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent that the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be pre-empted by section 521(a) of the act." (43 Fed.Reg. 33182).

fectiveness of the device *or to any other matter included in a requirement applicable to the device under this chapter.*" 21 U.S.C. § 360k(a) (emphasis supplied). Even if the state statute did not relate to the effectiveness of the device, it clearly relates to another matter included in a federal requirement, i.e., the advertising requirement of 21 U.S.C. § 352(r). Accordingly, it is also pre-empted on this latter basis.

E. The state statute is not to be deemed exempt from pre-emption.

Appellees' argument that the statute is automatically exempt because it is more stringent than the federal requirements is not correct. The fact that the state statute is more stringent means that the F.D.A. *may* grant an exemption, not that it is required to do so. (21 U.S.C. § 360k(b)).

F. Regulation of hearing aid advertising is within the jurisdiction of the F.D.A.

Appellees represent that the F.D.A. has found that ". . . regulation of hearing aid sales practices, including advertising, were [sic] not within the scope of its authority but would be left to the Federal Trade Commission. . . ." (Motion, p. 16; see also pp. 23-24). This is a misstatement of the law and of the F.D.A.'s position. What the F.D.A. actually said was, in sum and substance, as follows:

> *"Section 502(r) gives FDA jurisdiction for regulating certain specified advertising of restricted devices,* and the section concurrently removes FTC authority to apply the sanctions of court injunction or criminal penalties under sections 12 through 15 of the Federal Trade Commission Act to prevent these acts. It is the Commissioner's opinion, however, that section 502(r) limits FTC authority only to the extent specifically stated in the section, i.e., section 502(r) applies only to restricted devices and only to possible FTC use of court injunctions or criminal penalties to prevent false advertising relating to the items of information specified in section 502(r). Moreover, section 502(r) does not extend to, or in any way limit, any other authority of FTC related to the regulation of the sale of devices, such as the authority provided to FTC under section 5 of the Federal Trade Commission Act (5 U.S.C. 45) to prevent unfair or deceptive acts or practices.
>
> "In sum, it is the Commissioner's opinion that the net effect of section 502(r), as of the comparable provision under section 502(n) relating to prescription drugs, is to enable each agency to approach the regulation of restricted devices from the perspective of its particular statutory mandate. It is also the Commissioner's belief that both agencies will continue, as they have in the past, to work together in pursuit of their separate but closely related mandates. The Food and Drug Administration has long been aware of the FTC activities in the regulation of hearing aids that led to the FTC proposed rule, and the Commissioner believes these activities complement, rather than conflict with, this FDA regulation relating to labeling and conditions of sale of hearing aids. The Commissioner generally supports the FTC proposed rule and believes that the matters addressed therein are particularly within the FTC statutory mandate and expertise." (42 Fed.Reg. 9286, emphasis supplied).

As the foregoing statement indicates, the F.T.C. issued a proposed trade regulation rule in 1975 for the hearing aid industry. (See 40 Fed.Reg. 26646). The proposed rule dealt, *inter alia,* with advertising, but the F.T.C.'s jurisdiction

in this area is by no means exclusive. Appellees' claim that the F.D.A. has left the entire regulation of hearing aid advertising up to the F.T.C. (thereby abdicating its statutory responsibility) is in error.[3]

III

THE STATUTE INFRINGES UPON THE RIGHT TO FREEDOM OF SPEECH.

Appellees advance several arguments in support of their claim that no substantial free speech question is presented. Each of these arguments fails to meet the issue and should be rejected.

A. The Court of Appeal passed upon the issue.

Appellees argue in one breath that ". . . the court properly held that Dahlberg's advertisements fall outside the scope of the First Amendment." In the next breath they say that ". . . the court below correctly declined to rule on the constitutional issue raised here by appellant, and that issue is not properly before this Court." (Motion, p. 31).

Appellees' confusion is perhaps understandable because the Court of Appeal, after first stating that ". . . we need not reach this problem" (J.S., p. 31) went on to hold that (a) the advertisements before it were misleading and (b) "The injunction is thus proper." (J.S., p. 31). The obvious flaw in this holding is that the premise simply does not support the conclusion. A finding that certain pieces of advertising are misleading will obviously not support an injunction against *all* advertising of the same kind, without regard to its truth or falsity.

[3]The F.T.C. has never finally adopted any trade regulation rules for the hearing aid industry.

In any case, the Court of Appeal has certainly rendered a decision on the free speech issue, and appellant should not be denied review of that decision simply because the court used confusing language in its opinion or because it failed to meet the issue before it in a clear and forthright manner. It is not necessary that the state court's denial of the federal claim "shall have been put in direct terms. . . ." "If the necessary effect of the judgment has been to deny the claim, that is enough." *New York ex rel. Bryant v. Zimmerman,* 278 U.S. 63, 67. See also *Chambers v. Mississippi* (1973) 410 U.S. 284, 290, n. 3, 35 L.Ed.2d 297, 93 S.Ct. 1038; *Street v. New York* (1969) 394 U.S. 576, 582, 22 L.Ed.2d 572, 89 S.Ct. 1354.

B. There is no compelling state interest sufficient to justify the denial of free speech.

Appellees argue that there is a compelling state interest in regulating advertising in the health care area sufficient to justify the statute and the injunction. In support of these arguments they rely upon numerous lower court cases which pre-date this Court's decision in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.* (1976) 425 U.S. 748, 48 L.Ed.2d 346, 96 S.Ct. 1817, and therefore are not persuasive.

Appellees point with alarm at alleged "promotional gimmicks" which will create an "artificial demand" for hearing aids. These considerations have no basis in fact and are completely contrary to the philosophy of the *Virginia* case which favors the "free flow of commercial information." (425 U.S. at 763). Furthermore they ignore the fact that the F.D.A. regulations now require a medical evaluation by a licensed physician within six months before the pur-

chase of a hearing aid. The physician must provide the patient with a written statement indicating that the patient's hearing loss has been medically evaluated and that the patient may be considered a candidate for a hearing aid. The patient may waive the evaluation but only under specified conditions designed to protect against any possible overreaching by the hearing aid dispenser. (21 *C.F.R.* § 801.421).[4] This requirement, so greatly emphasized by appellees in their discussion of the pre-emption issue, but completely overlooked in respect to the free speech issue, virtually eliminates the potentially dangerous consequences of advertising envisioned by appellees.

C. Appellant's interest is not contrary to the interests of the hearing aid user.

Appellees assert that appella..., as a manufacturer, has a mere "pecuniary" interest in advertising which conflicts with the interest of the public. (Motion, p. 39). This charge is unfounded and unfair. When viewed in proper legal perspective the interests of the manufacturer and the potential hearing aid user are totally consistent, just as the interest of the pharmacist and the consumer in the *Virginia* case were totally consistent. Both will benefit from the free flow of commercial information. "... [W]e may assume that the advertiser's interest is a purely economic one. That hardly disqualifies him from protection under the First Amendment." (425 U.S. at 762).

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[4]This regulation, unlike the *proposed* exemption of the California statute, became final and effective on August 25, 1977.

D. Appellant should not be required to apply for permission to advertise under Health and Safety Code Section 26465.

Appellees argue that appellant has no standing to raise the First Amendment issue because it has never submitted any proposed advertising to the California Department of Health as supposedly contemplated by Health and Safety Code Section 26465. Appellant has already demonstrated in its Jurisdictional Statement the constitutional defects in Section 26465, which operates in conjunction with Section 26463 as a prior restraint. (J.S., pp. 20-21, 25-26).

In addition, a careful examination of Section 26465 reveals that it could never even apply to hearing aid advertising. Under Section 26465, it is the drug or device which the Department must approve, not the advertising as such, and the Department may only authorize the drug or device to be advertised if it determines that it is safe and effective as "self-medication." In such case, it may be advertised as having "a curative or therapeutic effect." The F.D.A. has determined that a hearing aid is not a safe and effective device for self-medication. It is a "restricted device" which should be sold only to persons who have had a medical evaluation by a licensed physician resulting in a determination that they are candidates for a hearing aid. Furthermore, a hearing aid is not a curative or therapeutic device. It is a compensatory device. (Calif. Bus. and Prof. Code § 3305.) Accordingly, Section 26465 simply cannot apply to hearing aids or to their advertising and has no impact upon appellant's claim under the First Amendment.

CONCLUSION

The motion to dismiss or affirm should be denied, and the Court should note probable jurisdiction herein.

Dated: February 12, 1979.

MICHAEL P. CARBONE

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Attorneys for Appellants Dahlberg Electronics, Inc., and Detection Sciences, Inc.

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No. 78-421

In the Supreme Court of the United States

OCTOBER TERM, 1978

DAHLBERG ELECTRONICS, INC., ET AL., APPELLANTS

v.

GEORGE KIEVLAN, ET AL.

ON APPEAL FROM THE COURT OF APPEAL OF CALIFORNIA, FIRST APPELLATE DISTRICT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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Washington, D.C. 20530

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's invitation of November 27, 1978.

QUESTIONS PRESENTED

1. Whether either the injunction against appellants or the state statute on which it is based restrains commercial speech in violation of the First Amendment.

2. Whether the state statute on which the injunction is based has been preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*

STATUTES INVOLVED

Section 26460 of the California Health and Safety Code (West 1978 Cum. Supp.) provides:

> It is unlawful for any person to disseminate any false advertisement of any food, drug, device or cosmetic. An advertisement is false if it is false or misleading in any particular.

Section 26463 of the California Health and Safety Code (West 1978 Cum. Supp.) provides in pertinent part:

> It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:
>
> * * * * *
>
> (m) Diseases or disorders of the ear or auditory apparatus; including hearing loss and deafness.

Section 26465 of the California Health and Safety Code (West 1978 Cum. Supp.) provides:

> Whenever the [California Department of Health] determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health.

Section 521(a) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 360k(a), provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of of the device or to any other matter included in a requirement applicable to the device under this chapter.

STATEMENT

Appellants manufacture, advertise and sell hearing aids. Appellees, persons with impaired hearing, brought this suit against appellants in a California Superior Court seeking recission, damages and an injunction on the ground that appellants' advertisements were unlawful under Section 26463(m) of the California Health and Safety Code (J.S. Exh. B 37). The superior court found that the advertisements violated Section 26463(m) because they represented that appellants' hearing aids had an "effect in * * * [d]iseases or disorders of the ear or auditory apparatus, including hearing loss and deafness" within the meaning of the statute. The court rejected appellants' contention that Section 26463(m) prohibits only claims that hearing aids would have a curative effect on hearing disorders and does not prohibit claims that they would "merely compensate[ ] for the disorder or condition the way a prosthesis does for loss of a limb" (J.S. Exh. B 40). The court found no such distinction in the statute and enjoined appellants "from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and deafness" (*id.* at 44).

The Court of Appeal of California affirmed (J.S. Exh. A 28-36). Appellants argued in the court of appeal that the injunction, and Section 26463(m) on which it was based, violate the First Amendment because they prohibit appellants from making truthful claims about their hearing aids, *e.g.*, that they compensate for hearing loss. The court found it unnecessary to reach that claim, stating (J.S. Exh. A 31-32):

> The judgment enjoined [appellants] from advertising their hearing aids by representing that the hearing aids have any effect on diseases or disorders of the ear including hearing loss and deafness. The [California Health and Safety Code], section 26460,

> declares it is unlawful for any person to disseminate any false advertisement of any device and declares an advertisement is false if it is false or misleading in any particular. It is clear from the copies of the advertisements that are included in the record that the advertisements were misleading in that they convey the impression that the hearing aid would have a curative or therapeutic effect. The [appellants] in their brief concede that hearing aids do not have a curative or therapeutic effect. The *Virginia State Board of Pharmacy* [v. *Virginia Citizens Consumer Council, 425 U.S.* 748 (1976)] case is of no help to [appellants]. As a concurring opinion points out the court's decision did not preclude state and federal regulation of false or deceptive advertising. The injunction is thus proper.

The court also stated that the trial court correctly held that Section 26463(m) encompasses advertisements representing that hearing aids have a compensatory effect as well as those representing that they have a curative or therapeutic effect (J.S. Exh. A 30-31). Finally the court rejected appellants' argument that 21 U.S.C. 360k preempts Section 26463(m) of the California Health and Safety Code (J.S. Exh. A 32-34).

ARGUMENT

Appellants reiterate the arguments that they advanced in the California Court of Appeal: They maintain that Section 26463(m) and the injunction violate the First Amendment because they prohibit truthful advertisements and that Section 26463(m) is preempted by the Food, Drug, and Cosmetic Act. Appellants' arguments seem to us to misconceive the holding of the court of appeal.

As we read the court of appeal's opinion, the court held that the injunction prohibits only advertising claims that are false and misleading—*i.e.*, claims that appellants' hearing aids have a curative or therapeutic effect on hearing disorders (appellants conceded they have no such effect)—and that the injunction was therefore authorized by Section 26460 of the California Health and Safety Code. Given this conclusion, the court of appeal found it unnecessary to reach appellants' claim that the injunction and Section 26463(m) are unconstitutional. Because appellants do not contend that a state statute or injunction prohibiting false and misleading claims is unconstitutional or is preempted by federal law,[1] there is no properly presented federal question for this Court to consider. This Court reviews judgments, not opinions (*Herb* v. *Pitcairn*, 324 U.S. 117, 125-126 (1945)), and even if appellants' arguments about Section 26463(m) are

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[1]On the contrary, they concede the validity of Section 26460 (J.S. 21 n.9, 23). See also, *e.g.*, *Ohralik* v. *Ohio State Bar Assn.*, 436 U.S. 447 (1978); *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 383 (1977). Section 26460 is not preempted by the Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, for that statute preempts only state statutes that impose any requirement "different from, or in addition to, any requirement applicable under this chapter." 21 U.S.C. 360k(a). Section 26460, which prohibits false or misleading advertising, is identical to a prohibition in the federal statute, which provides that a "restricted device" (which includes hearing aids) shall be deemed to be misbranded if "its advertising is false or misleading in any particular." 21 U.S.C. 352(q).

correct, there is simply nothing wrong with a judgment based, as this one is, on Section 26460.[2]

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[2]Although the court discussed the scope of Section 26463(m) and appeared to suggest that that section prohibits more than false or misleading advertising claims, that discussion is *dicta*. Moreover, it is not clear the court believed that Section 26463(m) prohibits advertising claims that are not false and misleading. The court of appeal, like the superior court, rejected appellants' contention that Section 26463(m) prohibits only claims that hearing aids will have a "curative or therapeutic" effect on hearing disorders (which appellants conceded would be false) but does not prohibit claims that hearing aids may have a "compensatory effect" on hearing disorders (which appellants claimed is true). But the term "compensatory effect" is ambiguous, and appellants seem to avoid defining it with precision. A spectrum of claims may be posited. The statement "our hearing aids will cure your deafness" is clearly a curative claim that appellants concede would be false. The statement "our hearing aids amplify sound" could be viewed as a "compensatory effect" claim and would presumably be true and not misleading. Closer questions, however, are presented by such claims as "our hearing aids will help you hear clearly" or "our hearing aids may help you hear clearly." It is not clear whether such claims would fall within appellants' "compensatory effect" category, or whether they could be viewed as implying a curative effect, or whether in any event they would be false or misleading in view of studies showing that many people with hearing disorders cannot be assisted by hearing aids. Since, in our view, the court of appeal held that the injunction prohibits only false and misleading claims, it is unnecessary to understand fully its views about the scope of Section 26463(m) or the meaning of appellants' "compensatory effect" theory. Whether particular claims that appellants may make in the future will be false and misleading and thus in violation of the injunction is not ripe for review and would turn, in any event, on the particular facts. Moreover, if appellants have any uncertainty in that respect, they may seek clarification from the superior court. Cf. *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 394 (1965).

The court of appeal's conclusion that Section 26463(m) is not preempted by the Food, Drug, and Cosmetic Act (J.S. Exh. A 32-34) also is *dicta*. Whether that view was correct depends on whether the court believed that Section 26463(m) prohibits claims that are not false and misleading. If it believed that the section does prohibit truthful, non-misleading claims, then its conclusion that Section 26463(m) is not preempted is erroneous. Contrary to the court's belief (J.S. Exh. 34), hearing aids are classified by regulation as "restricted devices" within the meaning of 21 U.S.C. 352 and 360j(e)(1) (see 21 C.F.R. 801.420 *et seq.*). 21 U.S.C. 352(r) permits advertisements of restricted devices if they include "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications * * *," and 21 U.S.C. 360k(a) preempts any more stringent state law. The Secretary has not excepted Section 26463(m) from preemption under the provisions of 21 U.S.C. 360k(b).

CONCLUSION

The appeal should be dismissed for want of a properly presented federal question.

Respectfully submitted.

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Appellants.

On Appeal from the Court of Appeal of the State of California First Appellate District

BRIEF IN RESPONSE TO BRIEF FOR THE UNITED STATES AS AMICUS CURIAE AND SUPPLEMENTAL BRIEF

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BRIEF IN RESPONSE TO BRIEF FOR THE UNITED STATES AS AMICUS CURIAE AND SUPPLEMENTAL BRIEF

This brief is filed in response to the brief filed by the United States as amicus curiae on February 23, 1979 (hereafter "amicus brief"), and to call to the Court's attention, pursuant to Rule 16(5), the case of *Friedman v. Rogers,* ..... U.S. ....., 47 U.S. Law Week 4151 (decided February 21, 1979).

ARGUMENT

I.

RESPONSE TO BRIEF OF THE UNITED STATES AS AMICUS CURIAE ON THE ISSUE OF PREEMPTION.

In appellees' Motion to Dismiss or Affirm (hereafter "appellees Motion"), we urged the Court not to consider the preemption issue raised by appellants because the precise question of whether California Health and Safety Code section 26463(m) is preempted by the federal Food, Drug and Cosmetic Act (21 U.S.C. § 360K(a)), and if it is preempted, whether it should be exempt from preemption (21 U.S.C. § 360K(b)), is currently pending before the United States Food and Drug Administration (hereafter "FDA"). (Appellees' Motion, pp. 12-18). We noted that in section 360K of Title 21, Congress established the standards for preemption under the Food, Drug and Cosmetic Act, but expressly delegated the responsibility for determining whether state laws should be preempted to the FDA. *(Ibid).*

In the amicus curiae brief filed by the United States, however, the Solicitor General argues that Health and Safety Code section 26463(m) may be preempted. (Amicus Brief, p. 6). Appellees submit that this contention is erroneous.

As we explained in our Motion to Dismiss or Affirm (pp. 20-30), there is nothing inconsistent between California's prohibition of medical claims for hearing aids and the cautionary warnings required by the Food, Drug and Cosmetic Act. (21 U.S.C. § 352r). In the absence of a clear inconsistency making it impossible to comply with both

state and federal laws, the state law should not be preempted. *Jones v. Rath Packing Co.*, 430 U.S. 519, 540 (1977).

More importantly, the views expressed in the amicus brief contradict the position expressed by the Food and Drug Administration on July 26, 1978 in its proposed regulation exempting section 26463(m) from preemption. (43 Fed.Reg. 33182). The FDA's comments to the proposed regulation state:

> "The Commissioner is also proposing to exempt from preemption California's Health and Safety Code, section 26463(m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521(a) of the act." (*Ibid*).

Appellees submit that the opinion expressed by the FDA in its proposed regulation is the correct view of this issue.

II.

APPLICABILITY OF FRIEDMAN v. ROGERS.

On February 21, 1979, this Court held in *Friedman v. Rogers*, ... U.S. ....., 47 U.S. Law Week 4151, that a Texas statute prohibiting the practice of optometry under a trade name did not violate the First Amendment. The Court found that where there was "a significant possibility that trade names will be used to mislead the public" (.....

U.S. at ....., 47 U.S. Law Week at 4154), Texas' interest in protecting the public health of its residents justified the restrictions placed on the "commercial free speech" of optometrists.

Appellees submit that *Friedman v. Rogers* is directly applicable to the instant case, in the following respects:

(1) It reaffirms the Court's refusal to apply the "overbreadth" doctrine to commercial speech. (..... U.S. at ....., 47 U.S. Law Week at 4154).

(2) It affirms the opinion previously expressed by Mr. Justice Stewart that the "prior restraint" doctrine is inapplicable to commercial speech. (..... U.S. at ....., 47 U.S. Law Week at 4154).

(3) It holds that the states' power to regulate commercial speech in the interest of public health is not limited to speech that can be proven to be false or misleading, but extends to speech that has a significant possibility of misleading the public. This is precisely the California Legislature's intention in enacting Health and Safety Code section 26463(m). (*See,* Appellees' Motion, p. 34).

(4) As in *Friedman v. Rogers,* there is extensive documentation in the instant case of the grave problems addressed by the state regulatory scheme. (*See,* United States Department of Health, Education and Welfare, *A Report on Hearing Aid Health Care* (C.T. 125-194); *see also,* comments of the Food and Drug Administration, 42 Fed.Reg. 9286, February 15, 1977, and the sources cited therein; Federal Trade Commission, Bureau of Consumer Protection, *Hearing Aid Industry Staff Report* (September,

1978), summarizing and analyzing the evidence in FTC rulemaking proceeding (16 C.F.R. Part 440; 40 Fed.Reg. 26646, June 24, 1975). (43 Fed.Reg. 54103, November 20, 1978)).

Thus, *Friedman v. Rogers* confirms the constitutional validity of California Health and Safety Code section 26463(m).

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